

Reason for report:

EARNINGS

## CERULEAN PHARMA INC.

### 2Q Recap – Randomized Phase II Combination Trial in RCC Initiated

• **Bottom Line:** CERU reported 2Q14 financial results today and provided a pipeline update. Management announced initiation of a randomized Phase II trial of CRLX101 in combination with Avastin in renal cell carcinoma (RCC). Two key proof of concept data readouts from single arm CRLX101 combination studies are expected in 1Q15 from ovarian cancer and neoadjuvant rectal cancer trials respectively. CERU ended 2Q14 with \$64.3M in cash and equivalents. With an EV of only \$10M, CERU currently trades near cash and below its IPO price of \$7. We believe that CERU's lead product CRLX101 could potentially overcome limitations of approved camptothecin analogs, and the company's development rationale as part of combination regimen is strong. Three catalysts in 2015 could validate CRLX101's therapeutic potential. **Reiterate OP rating and \$13 PT.**

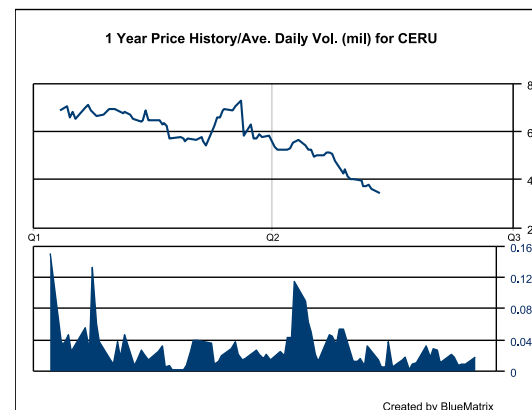
• **Pipeline programs on track.** A randomized Phase II trial evaluating CRLX101 in combination with Avastin in RCC has initiated slightly ahead of our expectations. Data from this trial continue to be expected in 4Q15. The trial will enroll 110 patients across 30 centers who have received at least two prior lines of therapy for metastatic RCC. Patients will be randomized to receive either CRLX101 plus Avastin or investigator's choice. Phase II single arm CRLX101 combination data with Avastin in ovarian cancer are expected in 1Q15. Phase I/II single arm CRLX101 combination data with Xeloda and radiation in neoadjuvant rectal cancer are also expected in 1Q15. The ovarian and rectal cancer data will inform randomized Phase II-go decisions for these indications. CRLX301 is expected to enter the clinic in 4Q14, with Phase I data expected in 4Q15.

• **CERU ended 2Q14 with \$64.3M in cash and equivalents.** This cash position is expected to fund the several single-arm trials of CRLX101, the recently initiated randomized Phase II trial of CRLX101 in combination with Avastin in RCC, and the planned Phase I trial of CRLX301. CERU reported a net loss of \$7.4M (vs. our estimate of an \$8.1M loss and consensus of a \$6.8M loss), and EPS of (\$0.44) vs. our estimate of (\$0.43) and consensus of (\$0.36).

#### Key Stats:

(NASDAQ:CERU)

<b>S&amp;P 600 Health Care Index:</b>	<b>1,281.85</b>
<b>Price:</b>	<b>\$3.46</b>
Price Target:	\$13.00
Methodology:	DCF analysis with 16% discount rate
52 Week High:	\$8.06
52 Week Low:	\$3.35
Shares Outstanding (mil):	20.1
Market Capitalization (mil):	\$69.5
Book Value/Share:	\$0.00
Cash Per Share:	\$3.19
Dividend (ann):	\$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A	--	--	--	--	0.0	--	--	--	--	(\$25.10)	NM
2014E - New	0.0A	0.0A	0.0	0.0	\$0.1	(\$3.70)A	(\$0.44)A	(\$0.45)	(\$0.56)	(\$2.13)	NM
2014E - Old	0.0A	0.0A	0.0	0.0	0.0	(\$3.70)A	(\$0.43)	(\$0.53)	(\$0.64)	(\$2.31)	NM
2015E - New	--	--	--	--	0.0	--	--	--	--	(\$1.73)	NM
2015E - Old	--	--	--	--	0.0	--	--	--	--	(\$1.67)	NM

Source: Company Information and Leerink Partners LLC Research  
Revenues in MM.  
GAAP EPS presented.

## INVESTMENT THESIS

We rate Cerulean Pharma (CERU) Outperform with a \$13/share price target representing a \$260M market capitalization. CERU is an oncology-focused company developing anti-cancer drugs based on its proprietary nanoparticle drug delivery platform. CERU's lead product CRLX101 has an attractive mechanism of action in our view that could overcome several limitations of approved agents. Based on our analysis we believe CRLX101 is active and CERU's development rationale is strong. Three major catalysts by 2H15 could validate CRLX101's therapeutic potential. We believe CRLX101 could address a \$1Bn US opportunity in 2030E and apply a 25% probability of success.

## VALUATION

We estimate a \$13 per share price target in 12 months for CERU, reflecting a \$260M market capitalization based on a discounted cash flow analysis. We use a 16% WACC as the discount rate, which we view as appropriate for CERU. We use probability weighted revenue assumptions. We model ~\$1.0Bn peak US CRLX101 sales in 2030E across three lead indications in 3rd line renal cell cancer, platinum-resistant ovarian cancer, and neoadjuvant rectal cancer.

## RISKS TO VALUATION

CERU faces significant clinical and regulatory risks since its main value driver is currently in multiple early stage investigator-sponsored clinical trials. Like many other developmental stage Biopharma companies, CERU faces manufacturing, competitive, commercial, regulatory, and safety risks, as well as risks to its intellectual property. Specifically, CERU faces regulator uncertainty on whether pCR will be accepted by the FDA as an approvable endpoint for a potential future neoadjuvant rectal cancer trial. CERU also faces financial risk and may need to raise dilutive capital near term. We expect the company's current cash balance to be sufficient to fund operations until late 2015.

CERU P&L (in \$MM)	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E
Product revenue	-	-	-	-	-	-	-	-	-
Other revenue	0.6	0.0	0.0	0.0	-	-	0.1	-	-
<b>Total Revenue</b>	<b>0.6</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	-	-	<b>0.1</b>	-	-
COGS	-	-	-	-	-	-	-	-	-
R&D Expense	15.8	9.7	1.5	2.6	6.0	8.0	18.1	35.0	55.0
SG&A Expense	6.4	6.2	1.5	2.0	3.0	3.5	10.0	11.0	12.1
Total Operating Expenses	22.2	15.9	3.0	4.7	9.0	11.5	28.2	46.0	67.1
Operating income (Loss)	(21.6)	(15.9)	(3.0)	(4.6)	(9.0)	(11.5)	(28.1)	(46.0)	(67.1)
Total other income (expense) - net	(0.5)	(1.3)	0.0	(2.8)	(0.1)	(0.1)	(3.0)	(0.3)	-
EBT	(22.1)	(17.1)	(2.9)	(7.4)	(9.1)	(11.6)	(31.1)	(46.3)	(67.1)
Tax	-	-	-	-	-	-	-	-	-
Net income (loss)	(22.1)	(17.1)	(2.9)	(7.4)	(9.1)	(11.6)	(31.1)	(46.3)	(67.1)
Accretion of redeemable convertible preferred stock	(0.1)	-	-	-	-	-	-	-	-
<b>Net loss attributable to common shareholders</b>	<b>(22.2)</b>	<b>(17.1)</b>	<b>(2.9)</b>	<b>(7.4)</b>	<b>(9.1)</b>	<b>(11.6)</b>	<b>(31.1)</b>	<b>(46.3)</b>	<b>(67.1)</b>
EPS - diluted	(36.4)	(25.1)	(3.70)	(0.44)	(0.45)	(0.56)	(2.13)	(1.73)	(2.51)
Common shares outstanding - diluted	0.6	0.7	0.8	16.9	20.1	20.6	14.6	26.8	26.8

CERU BS & CFS (in \$MM)	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E
Cash & equivalents	16.7	5.5	8.5	64.3	55.1	43.7	43.7	78.2	16.9
Debt	9.1	15.1	23.2	4.7	4.2	3.3	3.3	-	-

Change in Cash	1.4	(11.2)	3.0	55.8	(9.2)	(11.5)	38.2	34.5	(61.3)
<b>Cash from operations</b>	<b>(21.0)</b>	<b>(16.6)</b>	<b>(3.7)</b>	<b>(4.2)</b>	<b>(8.3)</b>	<b>(10.6)</b>	<b>(26.8)</b>	<b>(42.1)</b>	<b>(61.3)</b>
Net income (loss)	(22.2)	(17.1)	(2.9)	(7.4)	(9.1)	(11.6)	(31.1)	(46.3)	(67.1)
Share based comp	0.5	0.6	0.1	0.2	0.7	0.9	2.0	3.7	5.4
Non-cash interest expense	0.1	0.6	0.1	0.1	-	-	0.2	-	-
D&A	0.3	0.2	0.0	0.0	0.1	0.1	0.3	0.5	0.5
Other (Change in WC)	0.2	(0.9)	(1.1)	2.8	-	-	1.8	-	-
<b>Cash from investing</b>	<b>(0.2)</b>	<b>(0.0)</b>	<b>(0.0)</b>	<b>0.0</b>	-	-	<b>0.0</b>	-	-
Capex	(0.2)	(0.0)	(0.0)	(0.0)	-	-	(0.0)	-	-
Acquisitions	-	-	-	-	-	-	-	-	-
Other	-	-	0.0	0.0	-	-	0.0	-	-
<b>Cash from financing</b>	<b>22.5</b>	<b>5.4</b>	<b>6.7</b>	<b>60.0</b>	<b>(0.8)</b>	<b>(0.8)</b>	<b>65.0</b>	<b>76.6</b>	-
Equity issue (buyback)	12.9	0.0	0.0	60.0	-	-	60.0	80.0	-
Debt issue (principal payment)	9.6	5.4	7.7	(1.0)	(0.8)	(0.8)	5.0	(3.4)	-
Other	(0.0)	-	(1.1)	1.1	-	-	0.0	-	-

Source: SEC Filings and Leerink Partners Estimates

**CRLX-101**

Indication	Trial	Event	Timing
3rd/4th line mRCC	Phase I Avastin combination IST	Final data (ORR, PFS)	1Q15
	Phase II randomized Avastin combination	<b>ORR data</b>	<b>4Q15</b>
Platinum-resistant OC	Phase II Avastin combination IST	Single arm ORR data	1Q15
	Phase II/III randomized Avastin combination	<b>Final data (ORR, PFS)</b>	<b>3Q15</b>
Neoadjuvant rectal cancer		Initiate Phase II/III	2015
	Phase I/II CRT/Xeloda combination IST	ID MTD, launch Phase II single arm expansion	3Q14
		Single arm pCR data	1Q15
	Phase II randomized CRT/Xeloda combination	Initiate Phase II	1Q15
		<b>pCR data</b>	<b>4Q15</b>
HER2- gastric cancer		End-of-Phase II FDA meeting	1Q16
	Phase III randomized CRT/Xeloda combination	Initiate Phase III	2016
	Phase II PD single agent IST	trial ongoing	
2nd line SCLC	Phase II randomized single agent IST vs. topotecan	trial ongoing	

**CRLX-301**

Indication	Trial	Event	Timing
Solid tumors	Phase I	Initiate trial	4Q14
		Phase I data	4Q15

Source: Leerink Partners Estimates and Company Filings

## Disclosures Appendix

### Analyst Certification

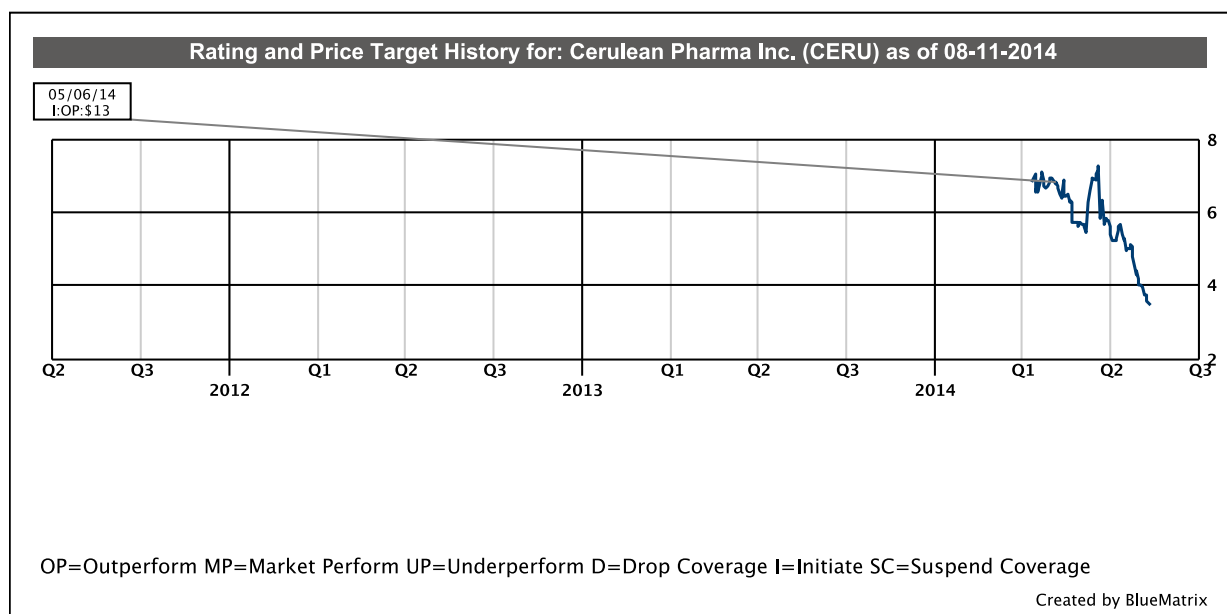
I, Michael Schmidt, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### Valuation

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Distribution of Ratings/Investment Banking Services (IB) as of 06/30/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	138	69.00	50	36.20
HOLD [MP]	62	31.00	2	3.20
SELL [UP]	0	0.00	0	0.00

## Explanation of Ratings

**Outperform (Buy):** We expect this stock to outperform its benchmark over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform in line with its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

## Important Disclosures

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**In the past 12 months, the Firm has received compensation for providing investment banking services to Cerulean Pharma Inc. .**

**Leerink Partners LLC makes a market in Cerulean Pharma Inc.**

**Leerink Partners LLC has acted as the manager for a public offering of Cerulean Pharma Inc. in the past 12 months.**

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