#### **OUTPERFORM**

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## Reason for report: **EARNINGS**



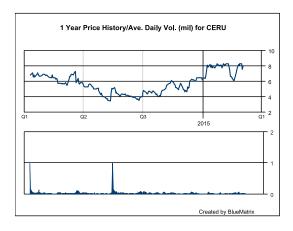
#### CERULEAN PHARMA INC.

4Q Recap - RCC Update Confirms Efficacy Signal; PT to \$18

- Bottom Line: CERU announced 4Q14 financial results Thursday after the close and provided a pipeline update. Mgmt reported positive data from the now fully enrolled investigator-sponsored trial (IST) for CRLX-101 in metastatic renal cell cancer (RCC) confirming the initial efficacy signal presented last year in a larger patient cohort. Mgmt also provided updates on two ongoing proof-of-concept combination studies in ovarian (OC) and neoadjuvant rectal cancer (RC). Data from the latter two trials are still too immature to inform randomized/controlled Phase II go/no-go decisions, which are expected late this year. The randomized/controlled Phase II trial in renal cell cancer in combination with Avastin continues to enroll; data now expected in mid-2016. Adjusting estimates to reflect 4Q14 results and raising PT to \$18 from \$13 previously.
- CRLX-101 Avastin combination IST data in RCC confirm efficacy signal seen previously. CERU reported a preliminary PFS of 9.9 months and an ORR of 23% in all 22 patients treated, which compares favorably to historic data in 3rd and 4th line RCC of ~3.5 months PFS and 2-4% ORR. Recall, CERU previously reported an ORR of 27% in 11 pts. We view the data overall encouraging and believe the data reflect positively on the ongoing randomized/ controlled Phase II trials with ORR and PFS data now expected in 3Q16. We note that some caution is warranted when interpreting data from single-arm, single-center open label trials, but we are slightly increasing the our probability of success assumption for CRLX-101 based on the new data. Full data will be presented at ASCO.
- OC combination data still immature. CERU reported first data from ongoing IST evaluating CRLX-101 plus Avastin in patients with relapsed OC. 1/9 patients achieved a partial response. Mgmt targets 15-25 patients total enrollment (likely year-end 2015) and set a 20% ORR as bar to advance the program into a randomized-controlled Phase II trial. In parallel, CERU and GOG Foundation will launch a study in combination with paclitaxel as part of a clinical research agreement announced on 3/4. Data from both trials will inform CRLX-101's path forward in OC.
- Addition of trial sites for neoadjuvant RC study should accelerate enrollment with Phase II-go/no go decision expected by year-end. Mgmt provided an encouraging update from the ongoing IST evaluating CRLX-101 with chemoradiotherapy (CRT). 2/8 patients achieved a pathologic complete response (pCR) vs. 1/3 reported previously. We continue to believe a 20-30% pCR rate would position the product competitively and justify launch of larger Ph II trials.
- Phase I for CERU's second candidate, CRLX-301 was initiated in December; first solid tumor data for the agent which achieves a 10x higher intratumoral docetaxel concentration vs. traditional product expected in 4Q15.

Key Stats: (NASDAQ:CERU)

S&P 600 Health C	1,646.56	
Price:		\$10.66
Price Target:	\$18.	00 from \$13.00
Methodology:	DCF analysis with 159	% discount rate
52 Week High:		\$10.87
52 Week Low:		\$3.35
Shares Outstandin	ıg (mil):	20.1
Market Capitalizati	ion (mil):	\$214.3
Cash Per Share:		\$2.20
Dividend (ann):		\$0.00
Dividend Yield:		0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2014A	0.0	0.0	0.0	0.0	\$0.1	(\$3.70)	(\$0.44)	(\$0.28)	(\$0.37)	(\$1.61)	NM
2015E - New	0.0	0.0	0.0	0.0	0.0	(\$0.43)	(\$0.53)	(\$0.63)	(\$0.69)	(\$2.27)	NM
2015E - Old					0.0					(\$1.71)	NM
2016E					0.0					(\$2.65)	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 \$18/share price target representing a \$360M valuation. CERU is an oncology-focused company developing anti-cancer drugs based on its proprietary nanoparticle drug delivery platform. CERU's lead product CRLX-101 has an attractive mechanism of action in our view that could overcome several limitations of approved agents. Based on our analysis we believe CRLX-101 is active and CERU's development rationale is strong. Clincial data in late 2015 and 2016 could validate CRLX-101's therapeutic potential. We believe CRLX-101 could address a \$1Bn US opportunity in 2030E and apply a 30% probability of success.

• CERU ended 4Q14 with \$51M in cash and equivalents and expects this will be sufficient to fund the company into 3Q16.

#### **VALUATION**

We estimate a \$18 per share price target in 12 months for CERU, reflecting a \$360M market capitalization based on a discounted cash flow analysis. We use a 15% 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 3Q16.

CERU P&L (in \$MM)	2012A	2013A	1Q14A	2Q14A	3Q14A	4Q14A	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Other revenue	0.6	0.0	0.0	0.0	-	-	0.1	-	-	-	-	-	-
Total Revenue	0.6	0.0	0.0	0.0	-	-	0.1	-	-	-	-	-	-
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D Expense	15.8	9.7	1.5	2.6	2.9	4.7	11.8	6.0	8.0	10.0	11.0	35.0	55.0
SG&A Expense	6.4	6.2	1.5	2.0	2.4	2.6	8.6	2.4	2.4	2.4	2.4	9.4	10.4
Total Operating Expenses	22.2	15.9	3.0	4.7	5.4	7.3	20.4	8.4	10.4	12.4	13.4	44.4	65.4
Operating income (Loss)	(21.6)	(15.9)	(3.0)	(4.6)	(5.4)	(7.3)	(20.3)	(8.4)	(10.4)	(12.4)	(13.4)	(44.4)	(65.4)
operating meanic (2000)	(22.0)	(13.3)	(5.0)	(1.0)	(3.1)	(7.5)	(20.5)	(0.1)	(20.1)	(12.1)	(13.1)	( ,	(03.1)
Total other income (expense) - net	(0.5)	(1.3)	0.0	(2.8)	(0.2)	(0.2)	(3.1)	(0.3)	(0.3)	(0.3)	(0.5)	(1.3)	(1.9
rotal other moonie (expense) net	(0.5)	(2.5)	0.0	(2.0)	(0.2)	(0.2)	(3.1)	(0.5)	(0.5)	(0.5)	(0.5)	(1.5)	(2.5)
EBT	(22.1)	(17.1)	(2.9)	(7.4)	(5.6)	(7.5)	(23.3)	(8.6)	(10.6)	(12.6)	(13.8)	(45.7)	(67.3
Tax	(22.1)	(17.1)	(2.5)	- (7.4)	(3.0)	(7.5)	(23.3)	(0.0)	- (20.0)	(12.0)	(13.0)	(+3.7)	(07.5)
Tux													
Net income (loss)	(22.1)	(17.1)	(2.9)	(7.4)	(5.6)	(7.5)	(23.3)	(8.6)	(10.6)	(12.6)	(13.8)	(45.7)	(67.3)
Accretion of redeemable convertible preferred stock	(0.1)	(17.1)	(2.5)	- (7.4)	(3.0)	- (7.5)	(23.3)	(8.0)	(10.0)	(12.0)	(13.8)	(43.7)	(07.5)
Net loss attributable to common shareholders	(22.2)	(17.1)	(2.9)	(7.4)	(5.6)	(7.5)	(23.3)	(8.6)	(10.6)	(12.6)	(13.8)	(45.7)	(67.3)
Net loss attributable to common shareholders	(22.2)	(17.1)	(2.3)	(7.4)	(3.0)	(7.5)	(23.3)	(0.0)	(10.6)	(12.0)	(13.0)	(43.7)	(67.3)
EPS - diluted	(36.4)	(25.1)	(3.70)	(0.44)	(0.28)	(0.37)	(1.61)	(0.43)	(0.53)	(0.63)	(0.69)	(2.27)	(2.65)
Er3 - diluted	(30.4)	(23.1)	(3.70)	(0.44)	(0.20)	(0.57)	(1.01)	(0.43)	(0.55)	(0.03)	(0.09)	(2.27)	(2.03)
Common above autotandina dilutad	0.6	0.7	0.8	16.9	20.1	20.1	14.5	20.1	20.1	20.1	20.1	20.1	25.4
Common shares outstanding - diluted	0.6	0.7	0.8	10.9	20.1	20.1	14.5	20.1	20.1	20.1	20.1	20.1	25.4
CERU BS & CFS (in \$MM)	2012A	2013A	1Q14A	2Q14A	3Q14A	4Q14A	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016
Cash & equivalents	16.7	5.5	8.5	64.3	57.8	51.2	51.2	59.5	49.8	38.3	36.6	35.6	64.1
Debt	9.1	15.1	23.2	4.7	3.9	3.3	3.3	15.1	15.0	15.0	26.0	26.0	26.0
Source: SEC Filings and Leerink Partners Estimates	3.1	15.1	25.2	7.7	3.3	5.5	3.3	15.1	13.0	13.0	20.0	20.0	20.0
Source. SECTIMINGS and LEETING Partners Estimates													
Change in Cash	1.4	(11.2)	3.0	55.8	(6.5)	(6.6)	45.7	8.3	(9.7)	(11.5)	(1.6)	(15.6)	28.4
Cash from operations	(21.0)	(16.6)	(3.7)	(4.2)	(5.6)	(5.6)	(19.1)	(7.8)	(9.7)	(11.5)	(12.6)	(41.7)	(61.6
Net income (loss)	(22.2)	(17.1)	(2.9)	(7.4)	(5.6)	(7.5)	(23.3)	(8.6)	(10.6)	(12.6)	(13.8)	(45.7)	(67.3
Share based comp	0.5	0.6	0.1	0.2	0.3	0.3	0.9	0.7	0.8	1.0	1.1	3.6	5.2
Non-cash interest expense	0.1	0.6	0.1	0.1	0.1	0.1	0.4	-					
D&A	0.3	0.2	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.5	0.5
Other (Change in WC)	0.3	(0.9)	(1.1)	2.8	(0.4)	1.5	2.9	0.1	0.1	0.1	- 0.1	0.5	0.5
Cash from investing	(0.2)	(0.9)	(0.0)	0.0	(0.4)	(0.1)	(0.2)	<u>:</u>				-	
Capex	(0.2)	(0.0)	(0.0)	(0.0)	(0.1)	(0.1)	(0.2)	-	-	-	-	-	-
Acquisitions	(0.2)	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)	(0.2)	-	-	-	-		-
Other	1 1	-	0.0	0.0	(0.0)	-			-	-	-	-	-
	22.5				. ,						- 11.0	20.4	
	22.5	5.4	6.7	60.0	(0.8)	(0.9)	64.9	16.1	-	-	11.0	26.1	<b>90.0</b> 90.0
Cash from financing													
Equity issue (buyback)	12.9	0.0	0.0	60.0	0.0	0.0	60.0	1.0	-	-			
•		0.0 5.4	0.0 7.7 (1.1)	60.0 (1.0) 1.1	0.0 (0.9) (0.0)	0.0 2.7	8.5 0.0	1.0	-	-	11.0	26.1	-

#### CRLX-101

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Indication	Trial	Event	Timing
3rd/4th line mRCC	Phase Ib/II Avastin combination IST	Final data (ORR, PFS)	ASCO 2015
	Phase II randomized Avastin combination	PFS and ORR data	3Q16
Platinum-resistant OC	Phase II Avastin combination IST	Updated data	late 2015
	Phase Ib paclitaxel combination GOG Foundation	Data	1Q16
Neoadjuvant rectal cancer	Phase Ib/II CRT/Xeloda combination IST	Updated data	late 2015

#### CRLX-301

Indication	Trial	Event	Timing
Solid tumors	Phase I	Phase I data	2015

Source: Leerink Partners Estimates and Company Filings

DCF analysis	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Sales					-	50	368	569	887	913	941	969	999	1,029	1,060	1,092	1,125
COGS	-	-	-	-	-	5	37	28	44	46	47	48	50	51	53	55	56
R&D	15	35	55	50	45	30	18	12	8	8	4	-	-	-	-	-	-
SG&A	9	9	10	11	13	80	84	142	222	228	235	242	250	257	265	273	281
OpEx	24	44	65	61	58	115	139	183	274	282	286	291	300	309	318	328	337
EBT	(23)	(46)	(67)	(63)	(60)	(65)	230	387	613	631	655	679	699	720	742	764	787
Tax	-	-	-	-	-	-	-	97	153	158	164	170	175	180	185	191	197
NI	(23)	(46)	(67)	(63)	(60)	(65)	230	290	459	473	491	509	524	540	556	573	591
Periods	-	-	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
PVFCF	-	(46)	(59)	(48)	(40)	(37)	114	125	173	155	140	126	113	101	90	81	73
NPV	1,061																
Probability of success	30%																
P/V NPV	318																
Net cash	44																
Combined (\$M)	363																
Shares outstanding (M)	20																
Price Target (\$)	18																
Source: Leerink Partners Estimates																	



# **Disclosures Appendix Analyst Certification**

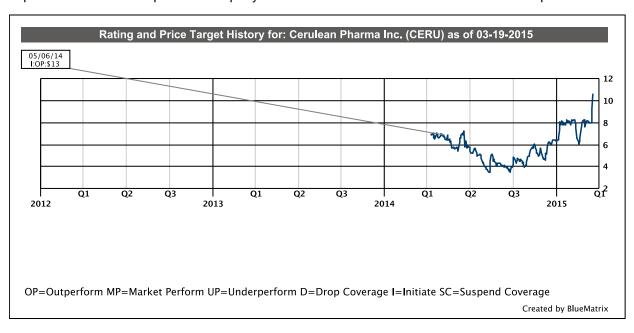
I, Michael Schmidt, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

#### **Valuation**

We estimate a \$18 per share price target in 12 months for CERU, reflecting a \$360M market capitalization based on a discounted cash flow analysis. We use a 15% 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.

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Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14 IB Services							
Rating	Count	Percent	Count	Percent			
BUY [OP]	150	70.00	60	40.00			
HOLD [MP]	64	30.00	1	2.00			
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.

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

<u>Underperform (Sell):</u> 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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