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**OUTPERFORM** 

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**FLASH NOTE** 



#### CERULEAN PHARMA INC.

Minor CRLX-101 Update at ASCO

- Bottom Line: Cerulean provided a minor update at ASCO this weekend on the Phase II CRLX-101 monotherapy IST trial in relapsed ovarian cancer (Abstract 5581). Nine patients have now achieved progressionfree survival (PFS) at six months (vs. 6 patients reported in the ASCO abstract). No additional responses were reported. Recall this trial had already met its primary endpoint in January 2014 of achieving PFS at six months for at least 4 patients. CRLX-101 is currently being evaluated in a combination IST trial with Avastin in relapsed platinum-resistant ovarian cancer patients with initial data expected in 4Q14. Our investment thesis remains unchanged and we continue to view CRLX-101 as a safe and active agent based on these data.
- · Three additional patients achieved PFS at six months in the CRLX-101 monotherapy IST Phase II trial in relapsed ovarian cancer. Cerulean reported at ASCO this Saturday that 9 patients of 30 patients have now achieved PFS at six months vs. 6 patients reported in the ASCO abstract. Recall this trial had already previously met its primary endpoint in January 2014 of achieving PFS at six months for at least 4 patients. As was reported previously in the ASCO abstract, no drug-related serious adverse events, treatment discontinuations, or deaths occurred. Data among the platinum resistant patients (n=19) also remained the same, with 16% achieving durable partial responses (PRs) and 74% achieving net tumor reductions. This trial is a single arm Phase II IST of CRLX-101 as monotherapy in 30 advanced relapsed ovarian cancer patients conducted at Massachusetts General Hospital (Boston, MA). Enrollment was completed in July 2013. As of March 25, 2014, 15/30 patients (50%) had achieved net tumor shrinkages, with four patients having achieved RECIST-based partial responses (PRs) (14%).
- · Initial data from ongoing CRLX-101 plus Avastin combination IST trial expected in 4Q14. A combination trial of CRLX-101 in 43 patients with Avastin in relapsed platinum-resistant ovarian cancer was recently initiated. Initial data (ORR) will be available in 4Q14, with final analysis (ORR, PFS) expected in 3Q15. An ORR of 20% or better will trigger a Phase III go-decision, expected in late 2015.
- Three major catalysts are approaching by 2H15 that should validate CRLX-101's therapeutic potential. In our view, key derisking data points are: (1) randomized controlled Phase II data in 4Q15 in 3rd line RCC w/ Avastin, (2) single arm data in platinum-resistant 2nd/3rd line ovarian cancer (OC) in combination w/Avastin in 3Q15, and (3) randomized Phase II data in neoadjuvant rectal cancer (RC) in combination w/ radiation and Xeloda in 4Q15. Additional data points before that include single arm OC combo data in 4Q14, single arm RC data in 4Q14, and final single arm RCC combo data in 2Q15.

Key Stats:	(NASDAQ:CERU)
S&P 600 Health Care Index: Price:	1,266.01 \$5.71
52 Week High:	\$8.06
52 Week Low:	\$5.05
Shares Outstanding (mil):	19.0
Market Capitalization (mil):	\$108.5



	ASCO 2014 Abstract	ASCO 2014 Presentation
Patients enrolled	30	30
Safety		
Drug-related SAEs	0	0
Treatment Discontinuations	0	0
Deaths	0	0
Efficacy		
median PFS	161 days	161 days
# of patients achieving PFS ≥ 6 mos	6	9
# of platinum resistant patients with evaluable scans	19	19
achieved durable PRs	3/19 (16%)	3/19 (16%)
achieved net tumor reductions Source: CERU presentation	14/19 (74%)	14/19 (74%)



# **Disclosures Appendix Analyst Certification**

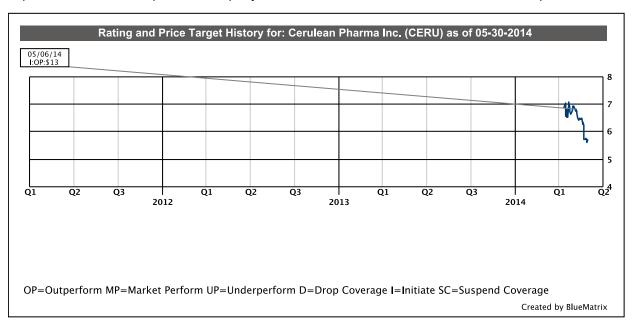
I, Michael Schmidt, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

#### **Valuation**

We estimate a \$13 per share price target in 12 months for CERU, reflecting a \$240M 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 CRLX-101 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.





	Distribution of Ratings/Investment Banking Services (IB) as of 03/31/14 IB Serv./Past 12 Mos.				
Rating	Count	Percent	Count	Percent	
BUY [OP]	131	68.23	46	35.11	
HOLD [MP]	61	31.77	3	4.92	
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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MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.



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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