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OUTPERFORM

Reason for report:

FLASH NOTE

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CERULEAN PHARMA INC.

CRLX101 Phase 1b Update Indicates Combineability in w/ Radiochemotherapy

• **Bottom Line:** Yesterday, CERU announced the presentation of CRLX101 Phase Ib and preclinical data at the ASCO 2015 Gastrointestinal Cancers Symposium. The Phase 1b trial is an investigator-sponsored trial (IST) evaluating CRLX101 in combination with Xeloda and radiotherapy in non-metastatic rectal cancer in the neoadjuvant setting. No dose-limiting toxicities (DLTs) have been observed to date in either the 12mg/m2 dose cohort (n=3) or the 15mg/m2 dose cohort (n=7), which has been the single agent CRLX101 MTD. We believe the positive safety data demonstrated so far and initial signs of efficacy observed at the lower 12mg/m2 dose of CRLX101 are reassuring. Recall, an irinotecan-CRT combination has not been clinically feasible due to severe toxicities. Mgmt expects to report response rates of the 15mg/m2 arm at the upcoming earnings call (March). The IST will be entering the Phase II portion of the trial, which has a target accrual of 53 patients. CERU believes a pCR rate of 30% would support a go-decision to trigger a large randomized company-sponsored Phase II trial. **Reiterate Outperform.**

• **Phase 1b data evaluating neoadjuvant CRLX101 in combination with Xeloda and radiotherapy in non-metastatic rectal cancer confirm safety.** The Phase 1b enrolled 3 patients in the 12mg/m2 dose cohort and 7 patients in the 15mg/m2 dose cohort. As we have noted previously, in the 12mg/m2 dose cohort, one patient had a pathologic complete response (pCR) and two patients showed extensive treatment response. An update was provided on the 15mg/m2 dose cohort, where 5 patients have completed treatment and 2 patients are still under treatment and CERU expects to report response rates during the next earnings call in March. No DLTs have been observed in either cohort. 15mg/m2 is expected to be the maximum-tolerated dose and recommended Phase II dose. This IST will be entering the Phase II portion of the trial, which has a target accrual of 53 patients. CERU also presented preclinical evidence of synergy. In a preclinical model of rectal cancer chemoradiation, the addition of CRLX101 to 5-FU and radiation led to a delay in the doubling of tumor volume from 11 days (5-FU and radiation) to 25 days (CRLX101 plus 5-FU and radiation).

• **We continue to believe there is strong rationale for combining CRLX101 with Xeloda and radiotherapy in rectal cancer.** Recall that CRLX101 is a nanoparticle-drug conjugate containing camptothecin, a topoisomerase 1 inhibitor. Combinations of irinotecan (a camptothecin analogue) plus Xeloda or 5-FU plus radiotherapy have demonstrated pCR rates between 21% and 37% across various trials, which are greater than the pCR rates that have been demonstrated across various trials using Xeloda or 5-FU plus radiotherapy alone. However, the toxicity of irinotecan prevents its addition to this therapy beyond clinical trial settings. We believe the positive safety data demonstrated so far and initial signs of efficacy observed at the lower 12mg/m2 dose of CRLX101 are reassuring. Recall that management is looking for at least a 30% pCR rate to enter a larger company-sponsored Phase II randomized trial.

Key Stats:	**(NASDAQ:CERU)**
S&P 600 Health Care Index:	**1,455.59**
Price:	**$7.89**
52 Week High:	$8.25
52 Week Low:	$3.35
Shares Outstanding (mil):	20.1
Market Capitalization (mil):	$158.6

Please refer to pages 3 - 5 for Important Disclosures, Price Charts and Analyst Certification.

• **CERU will have multiple de-risking data readouts in 2015.** Single arm CRLX101 Avastin Phase II combination data in platinum-resistant ovarian cancer is expected in 1Q15. Management expects to report data on ~10 patients in 1Q15, and has set a 20% Objective Response Rate (ORR) as the bar to advance the program into a randomized, controlled trial. Data from the randomized Phase II trial evaluating CRLX101 in combination with Avastin in relapsed renal cell carcinoma (RCC) is expected to be announced in 4Q15. Patients are being randomized to receive either CRLX101 plus Avastin or investigator's choice. Phase I data in solid tumors from CERU's second candidate, CRLX301, is expected in 4Q15.

Disclosures Appendix

Analyst Certification

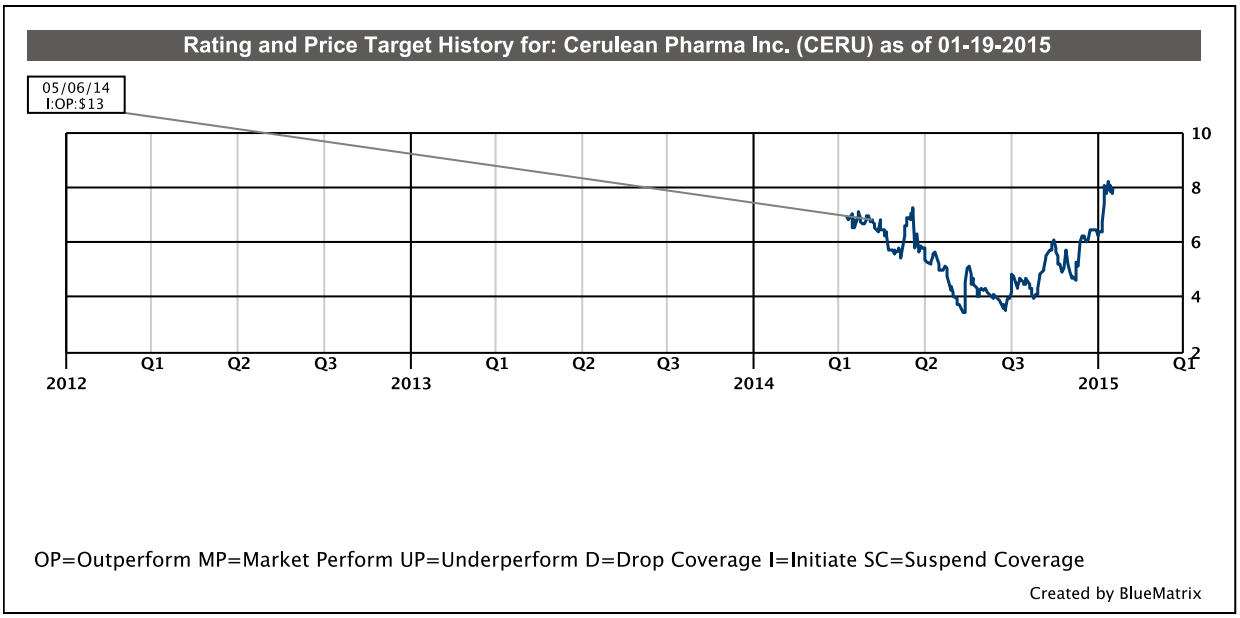
I, Michael Schmidt, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

We estimate a $13 per share price target in 12 months for CERU, reflecting a $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.



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Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	150	70.00	61	41.00
HOLD [MP]	64	30.00	0	0.00
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.
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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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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