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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported): March 19, 2015**

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**CERULEAN PHARMA INC.**

(Exact Name of Registrant as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-36395**  
(Commission  
File Number)

**20-4139823**  
(IRS Employer  
Identification No.)

**840 Memorial Drive**  
**Cambridge, MA**  
(Address of Principal Executive Offices)

**02139**  
(Zip Code)

**Registrant's telephone number, including area code: (617) 551-9600**

(Former Name or Former Address, if Changed Since Last Report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02. Results of Operations and Financial Condition.**

On March 19, 2015, Cerulean Pharma Inc. (the “Company”) issued a press release announcing, among other things, the Company’s operational highlights for the fourth quarter and year ended December 31, 2014 and anticipated corporate and clinical milestones for the remainder of 2015 and 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information provided under Item 2.02 of this Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 19, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CERULEAN PHARMA INC.

Date: March 19, 2015

By: /s/ Christopher D.T. Guiffre

Christopher D.T. Guiffre  
Chief Operating Officer

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 19, 2015.



## Cerulean Reports Fourth Quarter 2014 Corporate Highlights and Financial Results

*Phase 1b/2 trial of CRLX101 in renal cell carcinoma achieves primary endpoint*

*Closed debt facility for up to \$26.0 million with Hercules Technology Growth Capital in first quarter*

**CAMBRIDGE, Mass., March 19, 2015** – Cerulean Pharma Inc. (Nasdaq: CERU), a leader in Dynamic Tumor Targeting™, today provided an update on corporate activities during the quarter ended December 31, 2014, and reported progress with its clinical development programs.

“Today, Cerulean made the important announcement that the Phase 1b/2 trial of CRLX101 in combination with Avastin® in relapsed renal cell carcinoma, or RCC, that completed enrollment in the fourth quarter met its primary endpoint,” said Paul Friedman, M.D., Executive Chairman of Cerulean. “Additionally, patients in the trial receiving CRLX101 plus Avastin experienced median progression free survival, or PFS, of 9.9 months. Standard of care in the 3<sup>rd</sup> and 4<sup>th</sup> line RCC setting is roughly 3.5 months PFS. These results support the rationale for our ongoing randomized Phase 2 trial of CRLX101 plus Avastin in 3<sup>rd</sup> and 4<sup>th</sup> line RCC. We expect to report top-line primary endpoint data from this randomized trial in the second quarter of 2016.”

Friedman continued, “In addition to completing enrollment of the Phase 1b/2 RCC trial in the fourth quarter, Cerulean achieved another significant clinical milestone- our second platform-generated candidate, CRLX301, moved into clinical development when the first patient was treated in a Phase 1/2a trial in solid tumor malignancies in December 2014.”

### Fourth Quarter 2014 Corporate Highlights

- Completed enrollment in a Phase 1b/2 trial of CRLX101 plus Avastin in relapsed RCC, leading to the following positive top-line data reported today:
  - Met the primary endpoint of the trial (at least 50% of patients achieving four months PFS)
  - Demonstrated a preliminary median PFS of 9.9 months
    - Standard of care in 3<sup>rd</sup> and 4<sup>th</sup> line RCC is approximately 3.5 months PFS
  - Demonstrated a preliminary 23% objective response rate (ORR)
    - Standard of care in 3<sup>rd</sup> and 4<sup>th</sup> line RCC is 2-4% ORR
  - Combination has been generally well tolerated with no unexpected toxicities
- Launched a Phase 1/2a clinical trial of CRLX301:
  - Initiated first-in-human trial of CRLX301 at escalating doses to ascertain the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) in patients with advanced solid tumor malignancies
  - Conducting the trial in two cancer centers in Australia

### Key Subsequent Events

- Closed a debt facility for up to \$26.0 million with Hercules Technology Growth Capital, Inc., or Hercules, and sold \$1.0 million of Cerulean common stock to Hercules in a private placement
- Appointed Tiffany Crowell as Vice President of Clinical Operations

- Executed a clinical research agreement with GOG Foundation, Inc., to study CRLX101 in combination with weekly paclitaxel in relapsed ovarian cancer patients
- Announced top-line data (highlighted earlier in this release) from a Phase 1b/2 investigator-sponsored trial (IST) of CRLX101 plus Avastin in patients with relapsed RCC:
  - In an ongoing trial that completed enrollment in December 2014, the trial met its primary endpoint of at least 50% of patients achieving four months PFS
  - As of the date of the abstract submission to the American Society of Clinical Oncology (ASCO) Annual Meeting, the mPFS was 9.9 months
  - The ORR at the time of the ASCO submission was 23%
  - Seven patients were still being treated at the time of the ASCO submission
  - The Principal Investigator, Stephen Keefe, M.D., has submitted to present updated data at the 2015 ASCO Annual Meeting
  - Final data will be submitted for publication in a peer-reviewed journal later this year
- Announced interim clinical data from two ongoing ISTs:
  - In an ongoing Phase 2 trial of CRLX101 plus Avastin in patients with relapsed ovarian cancer:
    - One of the first nine patients enrolled in the trial achieved a partial response according to RECIST criteria
    - An additional one of nine patients achieved tumor reduction in excess of 20%
    - Nine of nine patients achieved stable disease or better
    - Four of nine patients are still on treatment
    - There have been no serious adverse events to date using Avastin at its standard dosing and CRLX101 at its MTD
    - Patients continue to enroll on this trial
  - In an ongoing Phase 1b/2 trial of CRLX101 plus chemoradiotherapy (CRT) in patients with non-metastatic rectal cancer:
    - Two of the first eight patients enrolled in the trial achieved a pathologic complete response (pCR)
    - Seven of eight patients achieved an AJCC/UICC tumor regression score of 0 or 1 on a scale of 0 to 3, with 0 being the best (a pCR) and 3 being the worst (poor treatment response)
    - Two other patients have been treated but have not yet had surgeries to determine their outcomes
    - There were no dose limiting toxicities in the nine patients enrolled in the Phase 1b stage of the trial, leading to establishment of the MTD and RP2D as 15 mg/m<sup>2</sup>
    - Patients continue to enroll on this trial, and the trial has advanced to the Phase 2 stage

### **Anticipated Upcoming Milestones**

During the remainder of 2015, Cerulean expects:

- The presentation of updated data for the Phase 1b/2 IST of CRLX101 plus Avastin in relapsed RCC by Dr. Keefe at the 2015 ASCO Annual Meeting
- The announcement of updated clinical results from the ongoing Phase 2 IST of CRLX101 plus Avastin in relapsed ovarian cancer

- The announcement of updated clinical results from the ongoing Phase 1b/2 IST of CRLX101 plus CRT in non-metastatic rectal cancer
- The announcement of clinical results from the ongoing Phase 1 trial of CRLX301

In 2016, Cerulean expects:

- The announcement of clinical results from the planned Phase 1b trial with GOG Foundation of CRLX101 plus weekly paclitaxel in relapsed ovarian cancer
- The announcement of the PFS endpoint and ORR data from the Phase 2 randomized RCC trial

### **Brief Financial Summary**

As of December 31, 2014, Cerulean had cash and cash equivalents of \$51.2 million. In January 2015, the Company entered into a loan and security agreement with Hercules for a term loan of up to \$26.0 million and sold \$1.0 million of Cerulean common stock to Hercules in a private placement.

Cerulean estimates that its current cash and cash equivalents will fund operations into the third quarter of 2016 and allow it to fund:

- the ongoing randomized Phase 2 clinical trial of CRLX101 plus Avastin in RCC
- the Phase 2 IST of CRLX101 plus Avastin in relapsed ovarian cancer
- the Phase 1b/2 IST of CRLX101 plus CRT in non-metastatic rectal cancer
- the Phase 1 clinical trial of CRLX301 in solid tumors
- the planned Phase 1b clinical trial in collaboration with GOG Foundation of CRLX101 plus weekly paclitaxel in relapsed ovarian cancer

More detailed financial information and analysis may be found in the Company's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 19, 2015.

### **Conference Call Information**

Paul Friedman, M.D., Executive Chairman, and Chris Guiffre, Chief Operating Officer, will conduct a conference call at 4:30 p.m. (ET) today to provide a business update and review the Company's fourth-quarter financial results. The call can be accessed by dialing (844) 831-3031 or (443) 637-1284 prior to the start of the call and referencing conference ID: 94512863. The conference call will also be webcast live over the Internet and can be accessed on the "Investors" section of the Cerulean website, [www.ceruleanrx.com](http://www.ceruleanrx.com). The webcast will be archived on the Company's website for two weeks.

### **About CRLX101**

CRLX101 is a dynamically tumor-targeted nanoparticle-drug conjugate (NDC) designed to concentrate in tumors and slowly release its anti-cancer payload, camptothecin, inside tumor cells. CRLX101 inhibits topoisomerase 1 (topo 1), which is involved in cellular replication, and hypoxia-inducible factor-1a (HIF-1a), which research suggests is a master regulator of cancer

cell survival mechanisms thought to promote drug and radiation resistance. CRLX101 has shown activity in four different tumor types, both as monotherapy and in combination with other cancer treatments. CRLX101 is currently in Phase 2 clinical development and has been dosed in more than 250 patients.

### **About CRLX301**

CRLX301 is a dynamically tumor-targeted NDC designed to concentrate in tumors and slowly release its anti-cancer payload, docetaxel, inside tumor cells. In preclinical studies, CRLX301 delivers up to 10 times more docetaxel into tumors, compared to an equivalent milligram dose of commercially available docetaxel and was superior to docetaxel in seven of seven animal models, with a statistically significant survival benefit seen in five of those seven models. In addition, preclinical data show that CRLX301 had lower toxicity than has been reported with docetaxel in similar preclinical studies. CRLX301 is currently in Phase 1 clinical development.

### **About Cerulean Pharma**

The Cerulean team is committed to improving treatment for people living with cancer. We apply our Dynamic Tumor Targeting Platform to create a portfolio of NDCs designed to selectively attack tumor cells, reduce toxicity by sparing the body's normal cells, and enable therapeutic combinations. Our first platform-generated candidate, CRLX101, is in multiple clinical trials in combination with other cancer treatments, all of which aim to unlock the power of combination therapy. Our second platform-generated candidate, CRLX301, is in a Phase 1/2a clinical trial. For more information, please visit [www.ceruleanrx.com](http://www.ceruleanrx.com).

### **About Cerulean's Dynamic Tumor Targeting™ Platform**

Cerulean's Dynamic Tumor Targeting Platform creates NDCs that are designed to provide safer and more effective cancer treatments. We believe our NDCs concentrate their anti-cancer payloads inside tumors while sparing normal tissue because they are small enough to pass through the "leaky" vasculature present in tumors but are too large to pass through the wall of healthy blood vessels. Once inside tumors, our NDCs enter tumor cells where they slowly release anti-cancer payloads from within the tumor cells.

### **Cautionary Note on Forward Looking Statements**

Any statements in this press release about our future expectations, plans and prospects, including statements about the clinical development of our product candidates, statements about our estimated research and development expenses and sufficiency of cash to fund specified use of cash and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation of clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such



trials, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals, availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the “Risk Factors” section of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 19, 2015 and in other filings that we make with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligation to update any forward-looking statements included in this press release.

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