

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

---

**FORM 8-K**

---

**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): May 2, 2016**

---

**CERULEAN PHARMA INC.**

(Exact name of Registrant as Specified in Its Charter)

---

**Delaware**

(State or Other Jurisdiction  
of Incorporation)

**001-36395**

(Commission File Number)

**20-4139823**

(IRS Employer  
Identification No.)

**35 Gatehouse Drive  
Waltham, MA**

(Address of Principal Executive Offices)

**02451**

(Zip Code)

**Registrant's Telephone Number, Including Area Code: (781) 996-4300**

**Not Applicable**

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

---

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 Instructions 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))
- 
-

**Item 2.02. Results of Operations and Financial Condition.**

On May 2, 2016, Cerulean Pharma Inc. (the “Company”) issued a press release announcing, among other things, the Company’s operational highlights for the quarter ended March 31, 2016 and anticipated corporate and clinical milestones for the remainder of 2016. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

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 May 2, 2016.

---

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: May 2, 2016

By: /s/ Christopher D.T. Guiffre

Christopher D.T. Guiffre  
President and Chief Executive Officer

---

**EXHIBIT INDEX**

Exhibit No.	Description
99.1	Press release dated May 2, 2016.



## Cerulean Reports First Quarter 2016 Corporate Highlights and Financial Results

Conference Call Today at 4:30 p.m. ET

**WALTHAM, Mass., May 2, 2016** – Cerulean Pharma Inc. (NASDAQ:CERU), a clinical-stage company developing nanoparticle-drug conjugates (NDCs), today provided an update on corporate activities during the quarter ended March 31, 2016.

“During the first quarter, we announced groundbreaking clinical data for CRLX101 in the *Proceedings of the National Academy of Sciences (PNAS)*, which provides the first proof of mechanism in human cancer patients for our platform technology,” said Christopher D. T. Guiffre, President & Chief Executive Officer of Cerulean. “Last week, we continued our momentum by announcing initial clinical results from our collaboration with the GOG Foundation, Inc. where five of nine platinum-resistant ovarian cancer patients achieved RECIST responses. We look forward to Dr. Krasner’s oral presentation of these results at the Gynecologic Oncology 2016 Conference on May 19.”

Mr. Guiffre continued, “The rate of disease progression in patients appears to have slowed down recently in our blinded trial of CRLX101 in combination with Avastin® (bevacizumab) in relapsed renal cell carcinoma (RCC); accordingly, we now expect top-line results in the third quarter 2016.”

### First Quarter 2016 Corporate Highlights

- Announced publication of clinical data for CRLX101 in *PNAS* showing CRLX101 localizes selectively in human tumors, sparing adjacent healthy tissue
  - Data represent first human proof of mechanism for Cerulean’s platform technology
- Reported clinical data from the ongoing Phase 1/2a trial of CRLX301 in patients with refractory solid tumors at the 14th International Congress on Targeted Anticancer Therapies
  - Determined the maximum tolerated dose on a once-every-three-weeks (Q3W) dosing schedule

### First Quarter 2016 Financial Summary

**Cash Position** - As of March 31, 2016, the Company had \$60.5 million in cash and cash equivalents. Cerulean estimates that its current cash and cash equivalents are sufficient to fund its operating expenses, debt service and scheduled capital expenditures into the second quarter of 2017.

**R&D Expenses** - Research and development expenses for the first quarter were \$9.8 million, compared to \$5.0 million for the same period in 2015. The increase was due primarily to increased expenses related to ongoing clinical development programs, including our randomized Phase 2 RCC trial for CRLX101 and Phase 1/2a trial for CRLX301, and increased chemistry, manufacturing and control expenditures to support current and future clinical development.

G&A Expenses - General and administrative expenses for the first quarter were \$3.1 million, compared to \$2.7 million for the same period in 2015.

Net Loss Attributable to Common Stockholders - Net loss attributable to common stockholders for the first quarter was \$13.5 million, compared to net loss attributable to common stockholders of \$8.4 million for the same period in 2015.

More detailed financial information and analysis may be found in our Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission on May 2, 2016.

### **Key Developments Subsequent to the End of the First Quarter**

- Reported top-line data from ongoing trial with the GOG Foundation, Inc. of CRLX101 in combination with weekly paclitaxel in relapsed ovarian cancer
  - Full data to be presented in an oral presentation at the Gynecologic Oncology 2016 Conference on May 19
- Presented data for both CRLX101 and CRLX301 developments via five poster presentations at the American Association for Cancer Research (AACR) annual meeting
  - *Phase 2 trial of the NDC CRLX101 in combination with Avastin in patients with platinum-resistant ovarian cancer* (MGH poster)
  - *Tumor selective localization of CRLX101, an investigational nanoparticle-drug conjugate of camptothecin*
  - *CRLX101, an investigational nanoparticle-drug conjugate of camptothecin, demonstrates synergy with immunotherapy agents in preclinical models*
  - *A camptothecin-containing nanoparticle-drug conjugate combination with DDR agents provides a novel approach to increasing therapeutic index* (AstraZeneca poster)
  - *Pharmacokinetics of CRLX301, a novel nanoparticle-drug conjugate containing the payload docetaxel, in patients with refractory solid tumors*

### **Anticipated Upcoming Milestones**

During the remainder of the first half of 2016, Cerulean expects to:

- Announce first patient dosed in Phase 1b/2 trial for the Cerulean-AstraZeneca-National Cancer Institute collaboration to study potential synergy between CRLX101 and LYNPARZA™ (olaparib)
- Announce first patient dosed in Phase 2a trial of CRLX301 in solid tumors
- Report additional CRLX301 data from Phase 1 trial at American Society of Clinical Oncology (ASCO)

During the second half of 2016, Cerulean expects to:

- Report primary and secondary endpoint top-line data (PFS and ORR) from randomized Phase 2 RCC trial of CRLX101 in combination with Avastin
  - Report results from an ongoing clinical trial evaluating weekly dosing of CRLX101 alone and in combination with Avastin
-

· Report additional interim data from investigator-sponsored trials with CRLX101 in combination with Avastin in relapsed ovarian cancer and CRLX101 in combination with chemoradiotherapy in locally advanced rectal cancer

## **Conference Call Information**

Management will conduct a conference call at 4:30 p.m. (ET) today to provide a business update and review Cerulean's first 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: 79828954. The conference call also will 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 Cerulean's website for two weeks.

## **About CRLX101**

CRLX101 is a 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 also inhibits hypoxia-inducible factor-1 $\alpha$  (HIF-1 $\alpha$ ), which research suggests is a master regulator of cancer cell survival mechanisms. CRLX101 has shown activity in four different tumor types, both as monotherapy and in combination with other cancer treatments. CRLX101 is in Phase 2 clinical development and has been dosed in more than 350 patients. The U.S. FDA has granted CRLX101 Orphan Drug designation for the treatment of ovarian cancer and Fast Track designation in combination with Avastin in metastatic renal cell carcinoma.

## **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 similar to or better than 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 in Phase 1/2a 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 NDC clinical 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 NDC clinical 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.

### **About GOG Foundation, Inc. (GOG Foundation)**

The GOG Foundation, Inc. (GOG Foundation) is an independent international non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. Continuous evaluation of the GOG Foundation's processes is utilized in order to constantly improve the quality of patient care. The GOG Foundation conducts clinical trials for patients with a variety of gynecologic malignancies, including cancers that arise from the ovaries, uterus, cervix, vagina, and vulva. The GOG Foundation is a separate entity from the National Clinical Trials Network groups that are funded by the National Cancer Institute.

### **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 the sufficiency of our cash and cash equivalents to fund our operations, debt service and other scheduled expenditures 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 and completion 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 2, 2016, 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.

Avastin is a registered trademark of Genentech, Inc.

LYNPARZA is a trademark of the AstraZeneca group of companies.

### **Contact:**

Nicole P. Jones  
Director, Investor Relations and  
Corporate Communications  
[njones@ceruleanrx.com](mailto:njones@ceruleanrx.com)  
781-209-6385