# 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): November 16, 2015**

# CERULEAN PHARMA INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-36395** | **20-4139823** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **840 Memorial Drive**<br>**Cambridge, MA**<br>**(Address of Principal Executive Offices)** | **02139**<br>**(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (617) 551-9600**

**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 November 16, 2015, Cerulean Pharma Inc. (the "Company") issued a press release announcing, among other things, the Company's operational highlights for the three and nine months ended September 30, 2015 and anticipated corporate and clinical milestones for the remainder of 2015 and 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:

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated November 16, 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: November 16, 2015

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 November 16, 2015. |

**Cerulean Reports Third Quarter 2015 Corporate Highlights and Financial Results**

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

**CAMBRIDGE, Mass., November 16, 2015** – 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 September 30, 2015.

"During the third quarter, we strengthened our management team by appointing Adrian Senderowicz as Chief Medical Officer. Adrian's experience in the lab and clinic at NCI, as a team leader at FDA, in clinical development at AstraZeneca, leading the oncology regulatory group at Sanofi, as CMO of Tokai and Ignyta, and as a board member of Puma Biotechnology make him well suited to lead our NDCs toward registration," said Christopher D. T. Guiffre, President & Chief Executive Officer of Cerulean. "We also strengthened our Board of Directors by adding David Walt. David's scientific acumen and entrepreneurial experience will be important to us as we expand our pipeline of platform-generated NDCs. Our Dynamic Tumor Targeting™ Platform continues to deliver results, and we just presented data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics proving our mechanism of action in humans for the first time."

**Third Quarter 2015 Corporate Highlights**

Clinical Data

- Reported first patient dosed in Phase 1b trial with the GOG Foundation, Inc. of CRLX101 in combination with weekly paclitaxel in patients with relapsed ovarian cancer
  - Data from this trial are expected in H1 2016, allowing Cerulean to compare results from this combination with results from an ongoing investigator-sponsored trial (IST) of CRLX101 in combination with Avastin® (bevacizumab) in order to determine registration strategy for CRLX101 in relapsed ovarian cancer, an indication for which FDA has granted CRLX101 Orphan Drug Designation
- Reported CRLX101 in combination with Avastin met a pre-determined stage gate in a Phase 2 IST in patients with relapsed ovarian cancer and advanced to Stage 2 of the trial
  - Data from this trial show that the combination is active and generally well- tolerated and could represent an important new option for patients in an area of high unmet need, allowing Cerulean to consider this combination as one option for registration in relapsed ovarian cancer

Teambuilding

- Appointed Adrian Senderowicz, M.D., as Senior Vice President and Chief Medical Officer
- Appointed David R. Walt, Ph.D., University Professor, Robinson Professor of Chemistry, Professor of Biomedical Engineering, Professor of Genetics, Professor of Oral Medicine at Tufts University and Howard Hughes Medical Institute Professor, to Board of Directors

**Key Subsequent Events**

CRLX101 Clinical Data

- Presented final results of Phase 1b/2 IST of CRLX101 in combination with Avastin in relapsed renal cell carcinoma (RCC) at 14th International Kidney Cancer Symposium
  - Data from this trial led to launch of randomized Phase 2 trial in relapsed RCC
- Presented evidence of selective accumulation of CRLX101 in tumors versus healthy tissue and inhibition of CRLX101's molecular targets in tumor cells at 2015 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics
  - These data represent first proof of mechanism in humans for Cerulean's Dynamic Tumor Targeting Platform
- Reported interim data from 18 patients enrolled in Stage 1 of ongoing Phase 2 IST of CRLX101 in combination with Avastin in relapsed ovarian cancer

  *Investigator-reported activity data:*
  - 9 of 16 (56%) patients evaluable for progression free survival (PFS) at six months achieved at least six months PFS, exceeding the 20% rate expected in this setting
  - 3 of 17 (18%) patients evaluable for overall response rate (ORR) achieved a partial response under RECIST criteria
  - 14 of 17 (82%) patients evaluable for ORR achieved stable disease under RECIST criteria
  - 8 of 18 (44%) patients evaluable for CA 125 levels achieved at least 50% decrease in CA 125, a blood biomarker used to monitor ovarian cancer activity

  *Investigator-reported tolerability data:*
  - No dose limiting toxicities (DLTs); combination appears to be generally well- tolerated

  *Next steps:*
  - Enroll an additional 25 patients in Stage 2
  - Consider CRLX101-Avastin combination as one registration option in relapsed ovarian cancer
- Reported interim data from 22 evaluable patients in ongoing Phase 1b/2 IST of CRLX101 in combination with chemoradiotherapy in locally advanced rectal cancer

  *Investigator-reported activity data:*
  - 4 of 22 patients (18%) achieved a pathological complete response (pCR), which represents an AJCC/UICC tumor regression grading of 0 on a scale of 0 to 3
  - 8 of 22 patients (36%) achieved minimal residual disease, which represents an AJCC/UICC tumor regression grading of 1 on a scale of 0 to 3

  *Investigator-reported tolerability data:*
  - No DLTs; combination appears to be generally well-tolerated

  *Next steps:*
  - Enroll an additional 53 patients using weekly dosing schedule
  - If weekly dosing schedule significantly increases pCR rates, discuss with FDA the possibility of using pCR as an approval endpoint

CRLX301 Clinical Data

- Reported initial data from 14 evaluable patients in dose escalation stage of ongoing Phase 1/2a trial of CRLX301 in solid tumors
  - *Tolerability data:*
    - Completed five dosing cohorts in 14 patients with no DLTs
    - Highest completed dosing cohort is 75 mg/m$^2$ (standard dose for docetaxel) administered once every three weeks
    - Opened 90 mg/m$^2$ dosing cohort
    - Maximum tolerated dose (MTD) has not yet been determined
  - *Investigator-reported activity data:*
    - One patient with B-RAF mutant carcinoma of unknown origin who previously failed prior B-RAF-directed therapy has experienced tumor shrinkage as measured per CT scans and experienced tumor shrinkage per RECIST with 13% decrease of target lesions and 35% decrease of non-target lesions from baseline
  - *Next steps:*
    - Continue to enroll patients in dose escalation stage of trial until MTD is determined for (1) once every three weeks dosing and (2) weekly dosing
    - Commence Phase 2a portion of trial in H1 2016 and further explore both dosing schedules

CRLX101 Clinical Development

- Completed enrollment of randomized Phase 2 trial of CRLX101 in combination with Avastin in 3$^{rd}$ and 4$^{th}$ line RCC
  - Data from this trial are expected in H1 2016, and assuming positive data, Cerulean expects to launch a Phase 3 trial in H2 2016 of CRLX101 in combination with Avastin in 3$^{rd}$ and 4$^{th}$ line RCC, an indication for which FDA has granted CRLX101 Fast Track Designation
- Reported first patient dosed in trial of CRLX101 to evaluate weekly dosing schedule
  - CRLX101 is dosed every other week at its MTD, and this study will determine whether CRLX101 is tolerable at increased dose intensity, which could increase therapeutic index

**Anticipated Upcoming Milestones**

In 2016, Cerulean expects to:

- Report primary and secondary endpoint data (PFS and ORR) from fully enrolled randomized Phase 2 RCC trial of CRLX101 in combination with Avastin during first half
- Report results from ongoing Phase 1b trial with GOG Foundation, Inc. of CRLX101 in combination with weekly paclitaxel in relapsed ovarian cancer during first half
- Report additional CRLX301 data from Phase 1 trial during first half
- Initiate Phase 2a trial of CRLX301 in solid tumors during first half
- Report results from ongoing clinical trial to evaluate weekly dosing schedule with CRLX101 during second half
- Report additional interim CRLX101 data from ovarian and rectal ISTs during second half
- Initiate Phase 3 trial of CRLX101 in combination with Avastin in patients with 3$^{rd}$ and 4$^{th}$ line RCC during second half

**Brief Financial Summary**

As of September 30, 2015, Cerulean had cash and cash equivalents of approximately $77.6 million. Cerulean estimates that its current cash and cash equivalents will fund operations into 2017.

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 November 16, 2015.

**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 third 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: 49083195. 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. 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-1α (HIF-1α), 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 300 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 currently 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 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.

**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 our 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 16, 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.

Avastin is a registered trademark of Genentech, Inc.

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