# 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): August 6, 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 August 6, 2015, Cerulean Pharma Inc. (the "Company") issued a press release announcing, among other things, the Company's operational highlights for the three and six months ended June 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 August 6, 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: August 6, 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 August 6, 2015. |

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

*Strengthened Balance Sheet with Underwritten Public Offering of Common Stock*

*Conference Call Today at 4:30 pm*

**CAMBRIDGE, Mass., August 6, 2015** – Cerulean Pharma Inc. (Nasdaq: CERU) today provided an update on corporate activities during the quarter ended June 30, 2015.

“Cerulean strengthened its balance sheet and team during the second quarter,” commented Christopher D. T. Guiffre, Cerulean’s President & Chief Executive Officer. “Now, we are focused on the data-rich period that Cerulean will experience over the next year, with multiple data readouts, including the first clinical data from CRLX301, which we expect in the fourth quarter of 2015, and results from the randomized Phase 2 trial of CRLX101 in combination with Avastin® in 3rd and 4th line renal cell carcinoma, or RCC, which we expect in the second quarter of 2016.”

“We are in a strong financial position to support our multiple clinical development programs with CRLX101 and CRLX301 and to leverage our platform technology to expand our development portfolio of nanoparticle-drug conjugates, or NDCs,” said Guiffre. “Cerulean is rapidly maturing as a platform-based, product-driven company, and we strengthened our team by adding Gregg Beloff, who brings extensive life sciences CFO experience to the management team, and Stuart Arbuckle, who brings deep oncology commercialization experience to our Board.”

**Second Quarter 2015 Corporate Highlights**

- Generated approximately $40.3 million in gross proceeds from an underwritten public offering of common stock, including full exercise of the underwriters’ overallotment option
- Granted Fast Track designation by the US Food and Drug Administration, or FDA, for CRLX101 in combination with Avastin in metastatic RCC in patients who have progressed through two or three prior lines of therapy
- Granted Orphan designation for CRLX101 by the FDA for the treatment of ovarian cancer
- Principal Investigator, Stephen Keefe, M.D., presented full data for Phase 1b/2 investigator-sponsored trial, or IST, of CRLX101 in combination with Avastin in metastatic RCC, or the RCC IST, at 2015 American Society for Clinical Oncology, or ASCO, Annual Meeting
- Appointed Gregg Beloff, JD, MBA, as Chief Financial Officer
- Appointed Stuart Arbuckle, Executive Vice President and Chief Commercial Officer at Vertex Pharmaceuticals Incorporated, to Board of Directors

**Key Subsequent Event**

- Dosed first patient in Phase 1b trial with GOG Foundation, Inc. of CRLX101 in combination with weekly paclitaxel in relapsed ovarian cancer

**Anticipated Upcoming Milestones**

During the remainder of 2015, Cerulean expects to:

- Report updated results from ongoing Phase 2 IST of CRLX101 in combination with Avastin in relapsed ovarian cancer
- Report updated results from ongoing Phase 1b/2 IST of CRLX101 in combination with chemoradiotherapy in non-metastatic rectal cancer
- Report initial clinical results from ongoing Phase 1 trial of CRLX301

In 2016, Cerulean expects to:

- Report clinical results from ongoing Phase 1b trial with GOG Foundation of CRLX101 in combination with weekly paclitaxel in relapsed ovarian cancer in the first half
- Report primary (PFS) and secondary (ORR) endpoint data from the ongoing randomized Phase 2 RCC trial during the first half
- Initiate Phase 2a trial of CRLX301 in patients with selected solid tumors in the first half
- Initiate Phase 3 trial of CRLX101 in combination with Avastin in patients with 3rd and 4th line RCC during the second half

**Brief Financial Summary**

As of June 30, 2015, Cerulean had cash and cash equivalents of $85.5 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 August 6, 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 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: 95865727. 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 August 6, 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 trademark of Genentech, Inc.

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