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 3, 2016

CERULEAN PHARMA INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) <u>001-36395</u>

(Commission File Number)

35 Gatehouse Drive Waltham, MA (Address of Principal Executive Offices)

02451 (Zip Code)

20-4139823

(IRS Employer

Identification No.)

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 November 3, 2016, 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, 2016 and anticipated corporate and clinical milestones in the coming quarters. 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 3, 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: November 3, 2016

By: <u>/s/ Christopher D.T. Guiffre</u>

Christopher D.T. Guiffre President and Chief Executive Officer Exhibit No.

Description

99.1

Press release dated November 3, 2016.



Cerulean Reports Third Quarter 2016 Financial Results and Provides Corporate Update

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

WALTHAM, Mass., November 3, 2016 – <u>Cerulean Pharma Inc.</u> (NASDAQ:CERU), a clinical-stage company developing nanoparticle-drug conjugates (NDCs), today provided an update on corporate activities for the quarter ended September 30, 2016.

"Cerulean experienced a clinical setback in the third quarter, but in October we demonstrated the promise of our NDC platform when we announced a collaboration with Novartis Institutes for BioMedical Research, Inc. (Novartis)," said Christopher D. T. Guiffre, President and Chief Executive Officer of Cerulean. "This collaboration gives us the opportunity to work with a world leader in oncology to create NDCs directed at five targets. We believe this collaboration validates the potential of our NDC platform as we move forward with our clinical development of CRLX101 as a potential best-in-class topoisomerase 1 inhibitor in combinations not previously possible, such as with weekly paclitaxel or LYNPARZATM (olaparib)."

Third Quarter 2016 Corporate Developments

- Reported that a randomized Phase 2 trial of CRLX101 in combination with Avastin® (bevacizumab) in 3rd and 4th line metastatic renal cell carcinoma did not meet its endpoint.
- Announced reduction in force of approximately 48% percent, which the Company expects to be substantially completed by end of 2016.
- Received Food and Drug Administration Fast Track Designation for CRLX101 in combination with paclitaxel, for the treatment of platinum-resistant ovarian carcinoma, fallopian tube or primary peritoneal cancer.

Key Developments Subsequent to the End of the Third Quarter

- Announced a five-target collaboration with Novartis to combine Cerulean's proprietary NDC technology with Novartisselected compounds. Cerulean received an upfront payment of \$5 million plus funding for five full-time equivalents. Cerulean also is eligible to receive preclinical, clinical, regulatory, and sales milestones for each of the five targets of up to \$233 million per target. In addition, Cerulean can earn single-digit to low double-digit tiered royalties on net sales for each NDC product commercialized by Novartis.
- Announced a firm commitment at-the-market equity facility for up to \$20 million with Aspire. In connection with entry into the facility, Aspire made an initial \$1,000,000 investment.

Third Quarter 2016 Financial Summary

Cash Position - As of September 30, 2016, the Company had \$38.1 million in cash and cash equivalents. The Company believes its cash and cash equivalents as of September 30, 2016, together with the \$1.0 million in proceeds from the initial sale of common stock to Aspire in October 2016 and the \$5.0 million upfront payment from Novartis received in October 2016, are sufficient to fund its planned operations for at least the next twelve months.

R&D Expenses - Research and development expenses were \$7.1 million for the third quarters of each of 2016 and 2015.

G&A Expenses - General and administrative expenses for the third quarter were \$2.4 million, compared to \$3.0 million for the same period in 2015.

Net Loss Attributable to Common Stockholders - Net loss attributable to common stockholders for the third quarter was \$10.0 million, compared to \$10.6 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 November 3, 2016.

Anticipated Upcoming Milestones

During 2017, Cerulean expects to:

- Report further results from the ongoing Phase 1b/2 clinical trial of CRLX101 in combination with weekly paclitaxel, in patients with platinum-resistant ovarian cancer
- Report initial results from the ongoing Phase 1/2 clinical trial of CRLX101 in combination with AstraZeneca's PARP inhibitor, LYNPARZA, in patients with advanced solid tumors
- Report initial results from the ongoing Phase 1/2a clinical trial of CRLX301 using a weekly dosing schedule in patients with advanced solid tumors

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: 7618037. The conference call also will be webcast live over the Internet and can be accessed on the "Investors" section of the Cerulean website, <u>www.ceruleanrx.com</u>. The webcast will be archived on Cerulean's website for two weeks.

About Cerulean Pharma

The Cerulean team is committed to improving treatment for people living with cancer. We apply our Dynamic Tumor TargetingTM Platform to create a portfolio of nanoparticle-drug conjugates (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 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 http://www.ceruleanrx.com/.

About CRLX101

CRLX101 is an 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. CRLX101 has shown activity in multiple 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 400 patients. The U.S. FDA has granted CRLX101 Orphan Drug designation for the treatment of ovarian cancer and Fast Track designation in combination with paclitaxel for platinum-resistant ovarian carcinoma, fallopian tube or primary peritoneal cancer.

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 a Phase 1/2a clinical trial.

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 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 November 3, 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.

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