
**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): March 10, 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))
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Item 2.02. Results of Operations and Financial Condition.

On March 10, 2016, 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, 2015 and anticipated corporate and clinical milestones for 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 March 10, 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: March 10, 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 March 10, 2016.



Cerulean Reports Fourth Quarter 2015 Corporate Highlights and Financial Results

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

WALTHAM, Mass., March 10, 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 December 31, 2015.

“Cerulean is rapidly approaching a key inflection point, with top-line results from our randomized Phase 2 clinical trial of CRLX101 in combination with Avastin® (bevacizumab) in relapsed renal cell carcinoma expected in the first half of 2016,” said Christopher D. T. Guiffre, President & Chief Executive Officer of Cerulean. “Beyond this important milestone are several clinical data readouts throughout 2016 spanning both of our clinical-stage NDC programs, CRLX101 and CRLX301. These milestones, together with the collaboration we announced this past quarter with AstraZeneca and the National Cancer Institute, provide a growing body of data validating the power of our Dynamic Tumor Targeting™ Platform and the broad applicability of NDCs in a variety of tumor types.”

Fourth Quarter 2015 Corporate Highlights

- Completed enrollment of a randomized Phase 2 trial of CRLX101 in combination with Avastin in relapsed renal cell carcinoma (RCC)
 - Top-line data expected H1 2016
 - Announced a clinical collaboration with AstraZeneca (AZ) and the National Cancer Institute (NCI) to evaluate the synergistic combination of LYNPARZA™ (olaparib) and CRLX101
 - Preclinical and correlative studies funded by AZ
 - Clinical study funded and run by NCI
 - Reported clinical data at the 2015 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics showing selective accumulation of CRLX101 in tumors versus adjacent healthy tissue and inhibition of CRLX101’s molecular targets in tumor cells
 - Data represent first human proof of mechanism for platform technology
 - Reported the first patient dosed in a clinical trial of CRLX101 to evaluate a weekly dosing schedule in advanced solid tumor malignancies
 - Exploring possibility of more intense dosing regimen
 - Announced relocation of office and laboratory space to AZ’s BioHub in Waltham, Massachusetts, effective January 1, 2016
 - Reduced rent expense and obtained expansion opportunities
 - Drew a second tranche under Loan and Security Agreement with Hercules Technology Growth Capital, Inc. (Hercules Loan Agreement) in the amount of \$6.0 million
 - Strengthened balance sheet
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Fourth Quarter 2015 Financial Summary

Cash Position - As of December 31, 2015, the Company had \$75.9 million in cash and cash equivalents as compared to \$51.2 million in cash and cash equivalents as of December 31, 2014. This includes a second tranche in the amount of \$6.0 million under the Hercules Loan Agreement, which we drew down in November 2015. Cerulean also completed an offering of common stock in April 2015 resulting in gross proceeds to the Company of approximately \$40.3 million. Cerulean estimates that its current cash and cash equivalents will fund operations into 2017.

R&D Expenses - Research and development expenses for the fourth quarter were \$7.2 million, compared to \$4.7 million for the same period in 2014. The increase was due primarily to increased expenses related to our ongoing clinical development programs, including our randomized Phase 2 RCC trial for CRLX101 and Phase 1/2a trial for CRLX301, both of which commenced in 2014.

G&A Expenses - General and administrative expenses for the fourth quarter were \$2.9 million, compared to \$2.6 million for the same period in 2014.

Net Loss Attributable to Common Stockholders - Net loss attributable to common stockholders for the fourth quarter was \$10.7 million, compared to net loss attributable to common stockholders of \$7.5 million for the same period in 2014.

More detailed financial information and analysis may be found in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 10, 2016.

Key Subsequent Event

- Cerulean declared the maximum tolerated dose (MTD) for CRLX301 in a once-every-three-weeks (Q3W) dosing regimen
 - Completed six dosing cohorts in Phase 1/2a trial in solid tumors and observed dose limiting toxicities in two of six patients at highest completed dosing cohort (90 mg/m²)
 - MTD and recommended Phase 2 dose (RP2D) administered Q3W is 75 mg/m²
 - § Adverse events observed to date appear to be less frequent and less severe than docetaxel at docetaxel's commercial dose
 - Cerulean now plans to initiate in H1 2016 (i) the Phase 2a portion of the study using Q3W dosing and (ii) the once-per-week (QW) dose escalation portion of the study to determine the MTD and RP2D for QW administration

Anticipated Upcoming Milestones

During the first 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
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- Report preliminary results from ongoing Phase 1b trial with the GOG Foundation, Inc. of CRLX101 in combination with weekly paclitaxel in relapsed ovarian cancer
- Report additional CRLX301 data from Phase 1 trial at the 14th International Congress on Target Anticancer Therapies, AACR, and ASCO
- Initiate Phase 2a trial of CRLX301 in solid tumors
- Announce first patient dosed in Phase 1b/2 trial for the Cerulean-AZ-NCI collaboration

During the second half of 2016, Cerulean expects to:

- Report preliminary results from an ongoing clinical trial to evaluate 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
- Initiate a Phase 3 trial of CRLX101 in combination with Avastin in patients with 3rd and 4th line RCC

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 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: 50675986. 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. 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 α (HIF-1 α), 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.

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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 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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