

TESARO, Inc.
Form 8-K
June 06, 2016

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): **June 4, 2016**

TESARO, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction of
incorporation)

001-35587
(Commission
File Number)

27-2249687
(I.R.S. Employer
Identification No.)

1000 Winter Street
Suite 3300
Waltham, Massachusetts

02451

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(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: **(339) 970-0900**

(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 Instruction 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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Section 7 Regulation FD

Item 7.01. Regulation FD Disclosure.

TESARO, Inc. (TESARO or the Company) provided an update on its clinical development pipeline during an investor briefing and webcast held in conjunction with the American Society for Clinical Oncology (ASCO) 2016 annual meeting. During the investor briefing, TESARO announced that (i) the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for an intravenous (IV) formulation of rolapitant and that the FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of January 11, 2017, (ii) a sufficient number of progression-free survival (PFS) events has been reached in its Phase 3 NOVA trial of niraparib in patients with ovarian cancer to trigger data analysis for both cohorts of the trial and that TESARO expects to announce top-line results later this quarter, and (iii) the FDA cleared its Investigational New Drug (IND) application for TSR-022, its anti-TIM-3 antibody candidate, and that a Phase 1 study for TSR-022 is planned to begin in mid-2016.

To the extent that statements contained in this Current Report are not descriptions of historical facts, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as may, will, expect, anticipate, estimate, intend, and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this Current Report, which include statements regarding the Company s expectation to have NOVA data in the second quarter of 2016 and the expected timing of initiation of the Phase 1 study for TSR-022, involve substantial risks and uncertainties that could cause results to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent regulatory submissions and approvals, the risk that the Company will not be able to announce NOVA data in the second quarter of 2016, and risks to the expected timing of the Phase 1 study for TSR-022. TESARO undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see TESARO s Annual Report on Form 10-K for the year ended December 31, 2015 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2016.

Section 8 Other Events

Item 8.01. Other Events.

Furnished as Exhibit 99.1 to this Current Report is a press release issued by TESARO, Inc. on June 4, 2016, including the information described in Item 7.01 above.

Section 9 - Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	TESARO, Inc. press release issued June 4, 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.

TESARO, Inc.

By: */s/ Joseph L. Farmer*
Joseph L. Farmer
Senior Vice President, General Counsel and Secretary

Dated: June 6, 2016

EXHIBIT INDEX

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