

TESARO, INC.

FORM 8-K (Current report filing)

Filed 06/12/17 for the Period Ending 06/09/17

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| Address | 1000 WINTER STREET, SUITE 3300 WALTHAM, MA 02451 |
| Telephone | (339) 970-0900 |
| CIK | 0001491576 |
| Symbol | TSRO |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**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 9, 2017**

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
Waltham, Massachusetts
(Address of principal executive offices)

02451
(Zip Code)

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

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:

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Section 7 — Regulation FD

Item 7.01 Regulation FD Disclosure .

TESARO, Inc. (“TESARO” or the “Company”) is providing an update regarding the status of a clinical trial of niraparib sponsored by Janssen Biotech, Inc., or Janssen, pursuant to the collaboration and license agreement entered into between TESARO and Janssen in April 2016. This trial, known as the GALAHAD trial, is a PHASE 2 efficacy and safety study of niraparib in men with metastatic castration-resistant prostate cancer and DNA-repair anomalies.

On June 9, 2017, Janssen updated the clinicaltrials.gov website to reflect the fact that Janssen had placed a temporary enrollment hold on pre-screening and screening of new subjects in the GALAHAD trial. The trial is not on a clinical hold, and this temporary enrollment hold is not due to any safety concerns. The GALAHAD trial has a planned enrollment of 160 patients. The study protocol defines the number of patients needed for each of several patient types. Since the study enrolled very rapidly, there is a temporary hold on enrollment so Janssen can assess the enrolled patients against the protocol criteria. This will ensure the appropriate balance of patient types are included in the intended study. Janssen anticipates re-opening enrollment soon.

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 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 in the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from clinical trials, uncertainties surrounding our ongoing discussions with and potential actions and approvals by regulatory authorities, and other matters that could affect our development plans and the availability or commercial potential of our drug candidates. 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, 2016 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2017.

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 12, 2017