TESARO, Inc. Form 8-K September 05, 2018

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): September 4, 2018

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 (IRS Employer Identification No.)

1000 Winter Street
Waltham, Massachusetts
(Address of principal executive offices)

02451 (Zip Code)

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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):
o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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 Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
Emerging Growth Company o
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. O

Section 7.01 Regulation FD

Item 7.01 Regulation FD Disclosure.

On September 4, 2018, TESARO, Inc. (TESARO or the Company) issued a press release announcing data from its JASPER clinical trial and that the Company has expanded to the second stage of the JASPER trial. JASPER is a Phase 2 trial evaluating the Company s product ZEJULA® in combination with an anti-PD-1 antibody in first-line, non-small cell lung cancer. A copy of the press release is attached to this current report as Exhibit 99.1 and is incorporated herein by reference.

The Company is also attending Citi s 13th Annual Biotech Day in Boston, Massachusetts on September 5, 2018. During a webcast fireside chat and other investor meetings at this event, the Company expects to utilize a presentation including the JASPER clinical trial data, other information regarding its clinical trial activities, and other general business information. The presentation also reiterates the Company s previously issued financial guidance for the second half of 2018. A copy of the presentation is available on the Investors Events and Presentations page of TESARO s corporate website, www.tesarobio.com.

To the extent that the statements in this report, including Exhibit 99.1, are not descriptions of historical facts regarding TESARO, 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, expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this report, including Exhibit 99.1, include, among others, statements regarding: statements regarding TESARO s financial guidance (including projected revenues, interest expense and cash levels) and ZEJULA s revenue outlook, statements regarding the potential size of market opportunities for TESARO s various products and product candidates, TESARO s lung cancer strategy, the design and expected timing of initiation, completion, and data readouts from TESARO s various ongoing and planned niraparib, TSR-042, TSR-033, TSR-022, and combination studies, including the progression of the JASPER trial, the expected timing of various regulatory filings, and potential indications for TESARO s products and product candidates. Forward-looking statements in this report, including Exhibit 99.1, involve substantial risks and uncertainties that could cause TESARO s future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, risks related to the acceptance of TESARO s products in the marketplace, competition, the uncertainties inherent in the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from clinical trials, uncertainties surrounding TESARO s ongoing discussions with and potential actions by regulatory authorities, uncertainties regarding our projected expenditures, risks related to manufacturing and supply, risks related to intellectual property, other matters that could affect TESARO s financial results, the results of TESARO s ongoing and planned development programs, and/or the availability or commercial potential of TESARO s products and 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, 2017 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2018.

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Section 9 Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 <u>TESARO, Inc. press release dated September 4, 2018.</u>

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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: September 5, 2018

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