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 15, 2017**

TESARO, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35587**	**27-2249687**
(state or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1000 Winter Street **Waltham, Massachusetts**	**02451**
(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))

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 ☐

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 8 — Other Events

Item 8.01. Other Events.

On September 15, 2017, TESARO, Inc. (the "Company") issued a press release announcing that the European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive opinion for the Company's marketing authorization application ("MAA") for ZEJULA® (niraparib) as a monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete response or partial response to platinum-based chemotherapy. This opinion will now be referred to the European Commission for a final decision on the MAA.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 September 15, 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: September 18, 2017

TESARO

TESARO RECEIVES POSITIVE CHMP OPINION FOR ZEJULA®

ZUG, SWITZERLAND, September 15, 2017 — TESARO, Inc. (NASDAQ: TSRO), an oncology-focused biopharmaceutical company, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for the Company's marketing authorization application (MAA) for ZEJULA® (niraparib) as a monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete response (CR) or partial response (PR) to platinum-based chemotherapy. This opinion will now be referred to the European Commission (EC), which grants marketing authorization for medicines in the European Union. Pending the decision by the EC, ZEJULA would be first oral, once-daily poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor approved in Europe for use in patients regardless of *BRCA* mutation or biomarker status.

ZEJULA was approved by the Food and Drug Administration (FDA) on March 27, 2017 and is marketed by TESARO in the United States, where it is the most frequently prescribed PARP inhibitor.

"ZEJULA was studied with the highest level of clinical rigor, and the Phase 3 NOVA trial generated unsurpassed efficacy results in patients with recurrent ovarian cancer, including women without germline *BRCA* mutations who have the most challenging prognosis and few treatment options," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "Today's positive CHMP opinion brings us one step closer to providing this important new medicine to a broad population of patients with recurrent ovarian cancer in Europe."

The ZEJULA marketing authorization application is supported by data from the ENGOT-OV16/NOVA trial, a double-blind, placebo-controlled, international Phase 3 study of ZEJULA that enrolled 553 patients with recurrent ovarian cancer who had achieved either a PR or CR to their most recent platinum-based chemotherapy. Approximately two-thirds of study participants did not have germline *BRCA* mutations. Progression in the NOVA study was determined by robust, unbiased, blinded central review to be the earlier of radiographic or clinical progression. ZEJULA significantly increased progression free survival (PFS) in patients with and without germline *BRCA* mutations as compared to the control arm. Treatment with ZEJULA reduced the risk of disease progression or death by 73% in patients with germline *BRCA* mutations (HR 0.27) and by 55% in patients without germline *BRCA* mutations (HR 0.45). The magnitude of benefit was similar for patients entering the trial with a PR or a CR.

The most common grade 3/4 adverse reactions to ZEJULA in the NOVA trial included thrombocytopenia (34%), anemia (25%), neutropenia (20%), and hypertension (9%). Following dose adjustment based on individual tolerability, the incidence of grade 3/4 thrombocytopenia was low; approximately 1% after month two. The majority of hematologic adverse events were successfully managed via dose modification, and discontinuation of therapy due to thrombocytopenia, neutropenia and anemia occurred in 3.3%, 1.9% and 1.4% of patients, respectively.

"This is an important milestone for TESARO, marking our second positive CHMP opinion for our portfolio in 2017. We are rapidly globalizing the Company's mission of providing transformative oncology therapies to those who need them most," said Orlando Oliveira, Senior Vice President and General Manager of TESARO International. "Upon final approval by the EC, we intend to launch ZEJULA across multiple countries in Europe where we already have an established, direct presence, beginning in the fourth quarter."

About Ovarian Cancer in Europe

Europe has one of the highest incidences of ovarian cancer in the world with approximately 45,000 women diagnosed there every year[1,2]. Ovarian cancer affects approximately 1.3 in 10,000 people in the European Union, where it is the sixth-most common cancer among women and the fifth-most frequent cause of cancer death among women[3,4]. Despite high initial response rates to platinum-based chemotherapy, approximately 85% of women with advanced ovarian cancer will experience a recurrence of the disease after first-line treatment. The efficacy of chemotherapy also diminishes over time.

About TESARO

TESARO is an oncology-focused biopharmaceutical company devoted to providing transformative therapies to people bravely facing cancer. For more information, visit www.tesarobio.com and follow us on Twitter and LinkedIn.

About ZEJULA (niraparib)

ZEJULA is an oral, once-daily poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor that is indicated in the U.S. for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The National Comprehensive Cancer Network (NCCN) added ZEJULA to the NCCN Clinical Practice Guidelines in Oncology Ovarian Cancer version 1.2017—April 12, 2017—as maintenance therapy for patients with platinum-sensitive disease who are in partial or complete response after completion of two or more lines of platinum-based chemotherapy. In preclinical studies, ZEJULA concentrates in the tumor relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent antitumor effect.

Forward Looking Statements

To the extent that statements contained in this press release 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," "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 release involve substantial risks and uncertainties that could cause our clinical development programs, 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 associated with competition in the PARP market, risks related to pricing and

(1) World Cancer Research Fund International. http://www.wcrf.org (Last accessed 14 September 2017)
(2) EUCAN (EU, EEA and Switzerland). http://eco.iarc.fr/eucan/CancerOne.aspx?Cancer=27&Gender=2 (Last accessed 14 September 2017)
(3) EUCAN. http://eco.iarc.fr/eucan/CancerOne.aspx?Cancer=27&Gender=2 (Last accessed 14 September 2017)
(4) CDC, https://www.cdc.gov/cancer/ovarian/statistics/index.htm (Last accessed 14 September 2017)

reimbursement, risks related to manufacturing and supply, risks related to intellectual property, and other risks and uncertainties that could affect the availability or commercial potential of ZEJULA. 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 June 30, 2017.

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