TESARO, INC.

FORM 8-K
(Current report filing)

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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 3, 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 **Suite 3300** **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 7 — Regulation FD

Item 7.01. Regulation FD Disclosure.

TESARO, Inc. ("TESARO" or the "Company") provided a business and clinical development pipeline update during an investor briefing and webcast held in conjunction with the American Society for Clinical Oncology (ASCO) 2017 annual meeting. During the investor briefing, TESARO announced that, among other things, (i) initial data from the Company's TOPACIO trial of niraparib plus KEYTRUDA® (pembrolizumab) demonstrated a disease control rate of 69% (9 of 13 patients), in patients with platinum-resistant ovarian cancer, (ii) results from a Phase 1 study of TSR-042, the Company's PD-1 antibody, demonstrated that, among the twenty one heavily pretreated patients in part 1 of the study, two had a partial response and five had stable disease, and no dose limiting toxicities were observed, (iii) the U.S. launch of ZEJULA™ is off to a strong start with approximately 800 new patient starts since approval and prescriptions written by more than 600 physicians, (iv) the U.S. Food and Drug Administration ("FDA") has accepted for review the re-submission of the Company's New Drug Application (NDA) for an intravenous (IV) formulation of rolapitant, that the FDA has classified it as a Class 2 resubmission and set a target action date under the Prescription Drug User Fee Act (PDUFA) of October 28, 2017, and that the Company is now planning a fourth quarter launch of VARUBI® IV, and (v) sales volume of VARUBI® oral tablets in the U.S. was 2,786 units and 3,179 units in April and May of 2017, respectively. Additional information related to these announcements is contained in the press released furnished as Exhibit 99.1 to this Current Report, and a replay of the webcast is available on the Investors section of the Company's website at tesarobio.com.

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, , uncertainties regarding certain expenditures, risks related to manufacturing and supply, risks related to intellectual property, 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

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 3, 2017, in connection with the investor briefing 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 3, 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 5, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	TESARO, Inc. press release issued June 3, 2017.

For Release on June 3, 2017 at 5:30 PM CT

TESARO PROVIDES BUSINESS AND PIPELINE UPDATE AT ASCO INVESTOR BRIEFING

- **Initial TOPACIO data for niraparib plus KEYTRUDA ® is indicative of potentially synergistic anti-tumor activity in platinum-resistant ovarian cancer**
- **Phase 1 results for TSR-042 show anti-PD-1 activity**
- **Three posters presented during ASCO describe additional analyses of NOVA data**
- **Robust demand continues for ZEJULA™**
- **VARUBI ® IV PDUFA date is October 25, 2017**
- **VARUBY ® oral launch now underway in Germany**

CHICAGO, ILLINOIS, June 3, 2017 — TESARO, Inc. (NASDAQ: TSRO), an oncology-focused biopharmaceutical company, today described initial data from the TOPACIO trial of niraparib plus KEYTRUDA ® (pembrolizumab) and results of a Phase 1 trial of TSR-042 during an investor briefing held in conjunction with the American Society for Clinical Oncology (ASCO) 2017 Annual Meeting. The Company also provided an update on its commercial businesses in the U.S. and Europe.

"ASCO represents an opportunity to showcase ZEJULA and the potential for it to positively impact the lives of women with recurrent ovarian cancer. Data presented earlier today during the conference further characterize the positive, durable treatment effects of ZEJULA and the clinical benefit in women who have residual disease following treatment with platinum-based chemotherapy. We are excited that the initial data from TOPACIO suggest a potential synergy between niraparib and an anti-PD-1 antibody, and look forward to evaluating this combination further in ovarian cancer and additional tumor types," said Lonnie Moulder, CEO of TESARO. "To date, there has been an overwhelmingly positive response by prescribers, patients and payors related to our U.S. launch and the potential for ZEJULA to benefit women with recurrent ovarian cancer. Our European organization has started filling orders for VARUBY in Germany, with other countries soon to follow. Pre-launch preparations are also underway to support the introduction of ZEJULA in Europe later this year, pending European Commission approval. In the U.S., demand for the oral formulation of VARUBI continues to increase and we look forward to a fourth quarter launch of VARUBI IV to extend our offering for patients who are undergoing emetogenic chemotherapy. Finally, our immuno-oncology programs are advancing at a rapid pace, led by the clinical study of TSR-042, our anti-PD-1 antibody, which we believe will form the basis for a registration of the drug in patients with MSI-H tumors, including endometrial cancer."

TOPACIO Data Demonstrate Activity in Platinum-Resistant Ovarian Cancer

TOPACIO is a Phase 1/2 clinical trial designed to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA ® (pembrolizumab) in patients with recurrent, platinum-resistant ovarian cancer or triple negative breast cancer. Phase 1 of TOPACIO consisted of a dose escalation study to evaluate an oral, once-daily dose of niraparib (200 milligrams or 300 milligrams) plus 200 milligrams of pembrolizumab administered intravenously on day one of

each 21-day treatment cycle. Endpoints included tolerability assessments, pharmacokinetic measures, and RECIST response rate.

In the dose escalation phase, a disease control rate of 69% was observed (9 of 13 evaluable patients), including 3 PRs and 1 CR, in patients with platinum-resistant ovarian cancer. The most common grade $\geq$ 3 adverse events included thrombocytopenia, anemia and neutropenia. At the recommended Phase 2 dose, one of seven patients experienced grade 3 thrombocytopenia and no significant overlapping toxicities were observed. A dose of 200 milligrams of niraparib once daily was selected for evaluation with pembrolizumab in Phase 2 of this study.

The first expansion cohorts of patients with platinum-resistant ovarian cancer (n=24) and triple-negative breast cancer (n=24) are now fully enrolled, and the second expansion cohorts for each tumor have been opened. Additional data from this trial are anticipated to become available during the second half of 2017.

The TOPACIO trial is being conducted in collaboration with Merck Sharp & Dohme B.V., a subsidiary of Merck & Co., Inc., which is providing support for the trial.

TSR-042 Phase 1 Results Show Anti-PD-1 Activity
The Phase 1 study of TSR-042, TESARO's anti-PD-1 antibody, is now complete. No dose limiting toxicities were observed. Among the 21 heavily pretreated patients in Part 1 of the study, two had a partial response (PR) and five had stable disease. Adverse events were commensurate with commercially-available anti-PD-1 therapies.

Following the identification of a fixed dose and patient-centric dosing schedule, the ongoing clinical trial of TSR-042 was expanded to enroll patients with metastatic microsatellite instability-high (MSI-H) endometrial cancer who have progressed following one or two prior chemotherapy treatments. During the first 12 weeks of treatment, TSR-042 is administered once every three weeks, followed by administration every six weeks until disease progression. The intent of this study is to support a request for accelerated approval and Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA). The primary endpoints of this trial are overall response rate (ORR) and duration of response, and secondary endpoints include disease control rate, progression free survival (PFS), and overall survival (OS). The addition of cohorts for patients with other tumor types, including those with MSI-H tumors, is also planned. This is the first clinical development program within a broader plan that includes potential label expansion trials of TSR-042 in multiple cancers in combination with ZEJULA, TSR-022, TESARO's anti-TIM-3 antibody, and TSR-033, TESARO's anti-LAG-3 antibody.

Niraparib Data Presentations at ASCO Demonstrate Positive, Durable Treatment Effect
Three posters describing additional data analyses from the Phase 3 ENGOT-OV16/NOVA trial of niraparib were presented today during the ASCO Annual Meeting.

- An analysis was performed to assess PFS and safety in patients who enrolled in the NOVA trial after a PR to their last platinum-based chemotherapy. Approximately 50% of all patients who enrolled in this trial entered with a PR, and results demonstrated that niraparib treatment provided significant benefit to these patients, with a treatment effect similar to that observed

in the overall study population in both the g *BRCA* mut cohort (HR=0.24 for patients with a PR vs. HR=0.27 for all patients) and non-g *BRCA* mut cohort (HR=0.35 for patients with a PR and HR=0.45 for all patients). The safety profile of niraparib-treated patients with a PR was similar to that of the overall study population.

- An assessment of platinum resistance status of patients in the NOVA trial was performed to better understand the population of patients that could benefit from treatment with niraparib. Approximately 50% of the patients in the placebo arm of this trial were found to have platinum-resistant disease following their last platinum-based therapy, as defined by progressive disease occurring less than six months following the last dose of chemotherapy. These findings suggest that approximately half of the total NOVA study population had disease that would have been considered platinum-resistant when they began maintenance treatment during the trial. The results of NOVA demonstrate that patients who had developed platinum-resistant disease after their last round of chemotherapy experienced benefit from niraparib maintenance.

- Additional analyses of NOVA assessed the longer-term efficacy of niraparib. Across both the g *BRCA* mut and non-g *BRCA* mut cohorts, treatment with niraparib increased the probability of PFS at 12, 18 and 24 months from randomization vs. placebo, as demonstrated by Kaplan-Meier estimates. The similarity in results for PFS2 minus PFS1 between niraparib and placebo suggests that niraparib had no decremental effect on the benefit of subsequent therapy.

Robust Demand for ZEJULA Continues

The U.S. launch of ZEJULA is off to a strong start, with more than 800 new patient starts since approval and prescriptions written by over 600 physicians. TESARO introduced ZEJULA in late April, following U.S. FDA approval for use as a maintenance treatment for women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response (CR or PR) to platinum-based chemotherapy. ZEJULA is the only PARP inhibitor to have demonstrated efficacy in patients without *BRCA* mutations in a randomized, Phase 3 trial and is the only PARP inhibitor to be approved by the FDA that does not require patient selection with a biomarker test. Pre-launch preparations continue in support of a European launch of ZEJULA by year-end 2017, pending European Commission approval. The niraparib early access program, or EAP, has already enrolled a number of patients in Europe, and more patients are anticipated to enter the program.

VARUBY Launches Ongoing in Europe; VARUBI IV PDUFA Date Established in the U.S.

Following the approval of VARUBY (oral formulation) by the European Commission for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults, VARUBY is now available in Germany. In the U.S., the FDA has accepted the Company's NDA re-submission for rolapitant IV and classified it as a Class 2 resubmission with a Prescription Drug User Fee Act (PDUFA) action date of October 25, 2017. TESARO is committed to bringing the intravenous formulation of VARUBI to physicians and patients to enable additional flexibility and choice of antiemetic regimens.

About ZEJULA (niraparib)
ZEJULA (niraparib) 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. 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.

ZEJULA (niraparib) Select Important Safety Information
Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) was reported in patients treated with ZEJULA in all clinical studies. Discontinue ZEJULA if MDS/AML is confirmed. Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia) have been reported in patients treated with ZEJULA. Do not start ZEJULA until patients have recovered from hematological toxicity caused by previous chemotherapy ($\leq$ Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months of treatment, and periodically after this time.

Hypertension and hypertensive crisis have been reported in patients treated with ZEJULA. Monitor blood pressure and heart rate monthly for the first year and periodically thereafter during treatment with ZEJULA. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for six months after receiving the final dose. Because of the potential for serious adverse reactions in breastfed infants from ZEJULA, advise a lactating woman not to breastfeed during treatment with ZEJULA and for one month after receiving the final dose.

In clinical studies, the most common adverse reactions included: thrombocytopenia, anemia, neutropenia, nausea, constipation, vomiting, abdominal pain/distension, mucositis/stomatitis, diarrhea, fatigue/asthenia, decreased appetite, headache, insomnia, nasopharyngitis, dyspnea, rash and hypertension.

Please see full Prescribing Information for additional Safety Information at www.zejula.com.

About VARUBI ® (rolapitant)
VARUBI is a substance P/neurokinin-1 (NK-1) receptor antagonist indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. NK-1 receptors are highly concentrated in the brain and bind neurokinin substance P. Activation of NK-1 receptors plays a central role in nausea and vomiting induced by emetogenic stimuli, including certain cancer chemotherapies. A Positron Emission Tomography (PET) study with rolapitant in normal, healthy volunteers demonstrated that rolapitant crosses the blood brain barrier and occupies brain NK-1 receptors at high levels for up to 120 hours. VARUBI has a half-life of approximately seven days, which may contribute to the ability of a single dose of VARUBI to cover the entire delayed CINV Phase

(25-120 hours). VARUBI is contraindicated in patients receiving thioridazine, a CYP2D6 substrate. The inhibitory effect of a single dose of VARUBI on CYP2D6 lasts at least seven days and may last longer. Avoid use of pimozide; monitor for adverse events if concomitant use with other CYP2D6 substrates with a narrow therapeutic index cannot be avoided. Please see full prescribing information, including additional important safety information, available at http://varubirx.com/.

About TSR-042
TSR-042 is a monoclonal antibody targeting PD-1 and was developed as part of the collaboration between TESARO and AnaptysBio, Inc. This collaboration was initiated in March of 2014, and is focused on the development of monospecific antibody drugs targeting PD-1, TIM-3 (TSR-022), and LAG-3 (TSR-033), in addition to a bi-specific antibody drug candidate targeting PD-1/LAG-3.

About Endometrial Cancer
Endometrial cancer is the most common type of uterine cancer, accounting for more than 95 percent of cases. Endometrial cancer develops in the lining of the uterus, called the endometrium. The annual number of new cases of endometrial cancer is estimated at 325,000 worldwide. The most common histologic form is endometrioid adenocarcinoma originating in the glandular tissue, which represents about 75-80% of diagnosed cases. In 2017, SEER(1) estimates 61,380 patients will be diagnosed with endometrial cancer, with approximately 30% or 18,414 being stage III/IV patients. Based on genomic characterization studies of endometrial cancer, 20-25% of patients have tumors with a microsatellite instability phenotype (MSI-H)(2). Microsatellite instability arises from a failure to repair replication-associated errors due to a defective DNA mismatch repair system. This failure allows persistence of mismatch mutations all over the genome, but especially in regions of repetitive DNA known as microsatellites, leading to increased mutational load that has been demonstrated to improve responses to anti-PD-1 therapies.(3),(4)

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.

Investor/Media Contact
Jennifer Davis
Vice President, Corporate Affairs & Investor Relations
+1.781.325.1116 or jdavis@tesarobio.com

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. Examples of forward-looking statements contained in this press release include, among others, statements regarding the expected timing of the approval and launch of VARUBI IV in the U.S., the expected timing of approval and commercial launches of ZEJULA in Europe, the expected timing of availability of additional TOPACIO data in the second half of 2017, our expected BLA submission and request for accelerated approval of TSR-042, our expectation to enroll more patients in our European EAP program for ZEJULA, and the design and expected timing of our various planned niraparib, TSR-042 and combination studies and other ongoing clinical trials. 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, 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 by regulatory authorities, uncertainties regarding regulatory approvals, including with respect to the ultimate approval and indication for niraparib in Europe, uncertainties regarding certain expenditures, risks related to manufacturing and supply, risks related to intellectual property, and other matters that could affect our development plans, 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.

KEYTRUDA ® is a trademark of Merck.

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(1) SEER: National Cancer Institute's Surveillance, Epidemiology, and End Results Program

(2) Kandoth C, Schultz N, Cherniack AD, et al: Integrated genomic characterization of endometrial carcinoma. Nature 497:67-73, 2013.

(3) Le DT, Uram JN, Wang H, et al: PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. N Engl J Med 372:2509-20, 2015.

(4) Westdorp H, Fennemann FL, Weren RD, et al: Opportunities for immunotherapy in microsatellite instable colorectal cancer. Cancer Immunol Immunother 65:1249-59, 2016.

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