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): **May 9, 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** (Address of principal executive offices)	**02451** (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 2 — Financial Information

Item 2.02 Results of Operations and Financial Condition .

On May 9, 2017, TESARO, Inc. (the "Company") held a conference call and webcast at 4:15 p.m. Eastern time to discuss its operating results for the quarter ended March 31, 2017 and provide an update on the Company's development programs. A copy of the prepared remarks used for the conference call is attached to this current report as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this report, including Exhibit 99.1, is being furnished to the Securities and Exchange Commission and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liabilities under that section. Furthermore, such information shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Section 9 — Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Prepared remarks for TESARO, Inc. conference call held May 9, 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: May 10, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Prepared remarks for TESARO, Inc. conference call held May 9, 2017.

Q1 2017 EARNINGS SCRIPT
TESARO, INC.

SLIDE 1 — TITLE SLIDE

OPERATOR:

Good afternoon, and welcome to the TESARO first-quarter 2017 conference call. At this time, all participants are in a listen-only mode. As a reminder, this call is being recorded and web cast. I'll now turn the call over to Jennifer Davis, Vice President of Investor Relations and Corporate Affairs at TESARO. Please go ahead.

SLIDE 2 — SAFE HARBOR STATEMENT

JEN:

Thank you, operator. Good afternoon, and thank you for joining us today to discuss our recent business progress and TESARO's first-quarter 2017 operating results. With me here today are our CEO, Lonnie Moulder; our president and COO, Dr. Mary Lynne Hedley; and our CFO, Tim Pearson. Earlier this afternoon, we issued a news release detailing our Q1 results. Please note that this news release and the slide presentation that we will refer to during this conference call are both available in the Investors section of our website, www.tesarobio.com.

Before we begin, I would like to remind you that discussions during this conference call will include forward-looking statements. These statements are subject to a number of risks and uncertainties that could cause our actual results to differ materially from those described in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statement for any reason. The factors that could cause actual results to differ are discussed in the press release issued today and in our SEC filings, including our annual report on Form 10-K for the year ended December 31, 2016.

During today's call, we may refer to certain non-GAAP financial measures that involve adjustments to GAAP figures. These non-GAAP financial measures are not a substitute for GAAP financial measures and are unlikely to be comparable to non-GAAP information provided by other companies. We believe non-GAAP measures may be useful to investors as a supplement to, but not as a substitute for, the applicable GAAP number.

I'd like to now turn the call over to Lonnie Moulder, CEO of TESARO. Lonnie?

SLIDE 3 — LONNIE'S TITLE SLIDE

LONNIE:

Thank you, Jen, and thank you everyone for joining us this afternoon.

SLIDE 4 — FIRST-QUARTER 2017 UPDATE

We are thrilled to be launching ZEJULA in the U.S. and, following our recent re-submission of the NDA for VARUBI IV, we are on track to expand our VARUBI franchise later this year. With approval of VARUBY oral by the European Commission last month, our international organization is preparing to introduce this important product on a country-by-country basis beginning in June. In addition, our niraparib expanded access program, or EAP, has enrolled the first patient in Europe, and many more patients are anticipated to begin treatment.

We continue to make excellent progress across our development portfolio, highlighted by significant progress in expanding our niraparib clinical development program into several new tumor types and in advancing our immuno-oncology candidates in the clinic. Mary Lynne will speak in greater detail about these programs and our plans later on in the call.

SLIDE 5 — ZEJULA U.S. LAUNCH NOW ONGOING

We were particularly gratified by the rapid FDA approval of ZEJULA and the launch is off to a phenomenal start. Based upon specialty pharmacy and specialty distributor data, approximately 500 prescriptions have been issued for ZEJULA by approximately 300 unique prescribers, with over 150 of those prescriptions occurring in the first week of May alone. This robust uptake is supported by prescriber enthusiasm for the strong ZEJULA clinical data, which demonstrated an unsurpassed PFS benefit in the gBRCA mutation setting and unprecedented benefit in patients without gBRCA mutations; resulting in a broad indication for woman with recurrent disease who responded to their most recent platinum regimen; immediate inclusion in the NCCN guidelines; no requirement for documentation of BRCA status prior to prescribing; and convenient, once daily dosing. ZEJULA is benefitting from the groundwork laid by the launch of other PARP inhibitors, and the recognition by clinicians that the ZEJULA landmark clinical data and approved indication offer women living with ovarian cancer an opportunity to receive benefit from a PARP inhibitor before their disease progresses.

The introduction of ZEJULA is the first of four planned product launches for TESARO during 2017, and this achievement underlines our broad capabilities to develop and commercialize innovative products, while working in pursuit of our mission to improve the lives of patients living with cancer.

SLIDE 6 — VARUBI STRATEGY TO DRIVE GROWTH

Turning to VARUBI. Our experience with VARUBI oral positions us well and creates momentum for the planned launch of VARUBI IV, which we expect in mid-2017. A successful

launch will allow us to reach the largest part of the U.S. market and, over time, extend the use of NK-1 receptor antagonists to the majority of patients receiving chemotherapy regimens, such as cisplatin, carboplatin and anthracycline/cyclophosphamide combinations, as recommended by the NCCN guidelines.

With that, I will now turn the call over to our CFO, Tim Pearson, for a review of our first quarter financial results. Tim?

SLIDE 7 — TIM'S TITLE SLIDE

TIM:

Thank you, Lonnie.

During the first quarter, approximately 6,300 units of VARUBI were shipped from specialty distributors and specialty pharmacies. As indicated in our fourth quarter call, we believe that approximately 20% of our Q4 2016 unit volume was attributable to purchases made in advance of year-end in anticipation of a price increase. After adjusting for those estimated purchases, we saw underlying unit growth of approximately 20% quarter on quarter, reflecting continued demand as demonstrated by new account orders and increased penetration at key large practices. As Lonnie mentioned, we are looking forward to bringing our IV formulation to U.S. customers shortly.

Turning now to our financial results….

SLIDE 8 — Q1 2017 FINANCIAL RESULTS

For the first quarter of 2017, TESARO reported total revenue of $3.1 million, which included $2.1 million in net product revenue related to sales of VARUBI oral to specialty pharmacy and specialty distributor customers, and approximately $1 million in revenue related to license and collaborations.

On January 1, 2017, TESARO implemented the new Financial Accounting Standards Board (or FASB) revenue recognition standards update known as Accounting Standards Update (or ASU) 606, which amended the guidance for accounting for revenue from contracts with customers. As a result, we have revised our fiscal year 2016 quarterly financial statements. Total revenues for full year 2016 were revised upward as a result of the implementation. More information will be available in our 10-Q filing later this evening.

Research and development expenses increased to $66.1 million for the first quarter, compared to $52.7 million in Q1 of 2016. The increase was driven primarily by higher costs related to the ongoing trials of niraparib, TSR-042 and TSR-022, advancement of our earlier-stage immuno-oncology portfolio, and increased headcount.

Selling, general and administrative expenses increased to $69.3 million for the first quarter, compared to $30.1 million in Q1 of 2016, primarily due to activities in support of the launches of VARUBI and ZEJULA in the U.S. and Europe, increased headcount, and higher professional service fees.

For Q1 of 2017, TESARO reported a net loss of $136.7 million compared to a net loss of $91.0 million for the first quarter of 2016.

As of March 31, 2017, TESARO had approximately $672 million in cash and cash equivalents, which reflects cash utilization during the first quarter of approximately $114 million, in line with our guidance. We continue to expect that our cash and cash equivalents balance will decrease by approximately $110 million to $120 million during Q2. This quarterly estimate excludes a total of $35 million of one-time regulatory milestones related to the approval of ZEJULA in the U.S. and the expected first commercial sale of VARUBY oral in Europe, which we expect to pay during the second quarter.

SLIDE 9 — MARY LYNNE'S TITLE SLIDE

With that, I'll hand the call over to Mary Lynne for an update on our development programs.

MARY LYNNE:

SLIDE 10 — PIPELINE CHART

Thank you, Tim. I'll now review each of our development programs and begin with niraparib.

SLIDE 11 — PIPELINE UPDATE, NIRAPARIB

Following FDA approval, we are excited to be launching ZEJULA as the first PARP inhibitor to be approved in ovarian cancer that does not require a companion diagnostic prior to treatment. Results from NOVA demonstrated the positive and durable treatment effects of ZEJULA in a broad population of patients, regardless of BRCA mutation status, and based on this result, we are now significantly expanding our development program for niraparib to include new clinical trials in ovarian, breast, and lung cancer.

SLIDE 12 — NIRAPARIB DELIVERS ANTI-TUMOR ACTIVITY

We believe that based on clear differences in the chemical and physiochemical properties between PARP inhibitors the clinical activity of one PARP inhibitor cannot be extrapolated across the class, particularly in patient populations that lack a BRCA tumor mutation.

In nonclinical studies, niraparib was shown to be highly permeable, it achieved higher concentrations in the tumor relative to plasma, and delivered selective, near complete, sustained PARP inhibition and a persistent anti-tumor effect. One dose of niraparib provides greater than 90% PARP inhibition for up to 24 hours in the tumor and produces tumor regressions where other PARP inhibitors do not. The high permeability of niraparib enables it to overcome the effect of efflux pumps such as Pgp, which can cause resistance to other PARP inhibitors.

In clinical studies niraparib was shown to be highly bioavailable, broadly distributed and slowly cleared. The combination of these effects may be most relevant to producing clinically meaningful outcomes in a broad patient population where the majority of patients do not have tumors with a BRCA mutation, and whose tumors may be inherently less sensitive to a PARP inhibitor.

We believe the treatment benefits of niraparib monotherapy can be expanded to the front line ovarian cancer setting and intend to establish our foothold here with PRIMA. PRIMA is a trial designed to assess the activity of niraparib vs placebo control in patients with newly diagnosed Stage ¾ ovarian cancer following a response to platinum. Patients are randomized 2:1, niraparib to placebo, and stratification factors include the homologous recombination deficiency or HRD,

status of the tumor. Primary endpoint analysis will include a hierarchical step down approach for progression free survival first in patients with HRD positive tumors, and if the results are statistically significant, we will assess PFS in the entire population.

QUADRA, also a monotherapy study of niraparib in the later lines of treatment for ovarian cancer patients, continues to enroll and we continue to plan for data at year-end.

SLIDE 13 — NIRAPARIB + PD-1

In addition to niraparib monotherapy, we are quite interested in studying the potential benefit of ZEJULA in combination with other anticancer agents, beginning with anti-PD-1. There is certainly more than one hypothesis to support the potential benefit of a niraparib anti-PD-1 combination, including activation of an innate cytoplasmic DNA sensing mechanism that detects breakdown products from stalled replication forks, such as those that occur following treatment with a PARP inhibitor. Signaling from this pathway results in upregulation of chemokines which entice T cells to traffic into the tumor where they can elicit their cytotoxic effects. Indeed, data are supportive of niraparib's effect on this pathway, including the enhanced tumor infiltration of CD8+ T cells and interestingly, co-treatment with niraparib and anti-PD-1 antibody produces synergistic effects in different murine tumor models.

The ongoing Phase 2 TOPACIO trial, is evaluating niraparib in combination with the anti-PD-1 antibody Keytruda in patients who have recurrent, platinum-resistant ovarian cancer or triple negative breast cancer. Patients with these tumors have demonstrated low response rates to anti-PD-1 antibody and PARP inhibitor monotherapies, and we hope to improve upon the clinical

activity with this combination approach. Cohort expansion for the two tumor types is underway and includes approximately 48 patients in each cohort. We are encouraged by the results that we have seen from this trial, and look forward to presenting data from a group of patients with recurrent ovarian cancer at our ASCO investor event and a future medical meeting.

We intend to capitalize on the findings from this study and the potential benefit of niraparib and anti-PD-1 therapy in multiple indications. First, we intend to initiate a Phase 3 trial of niraparib in combination with anti-PD-1 therapy in patients with newly diagnosed ovarian cancer as a means to strengthen our position in the front-line setting. In addition we have had multiple positive discussions with key opinion leaders about our intended study design for niraparib and anti-PD-1 therapy in patients with early metastatic triple negative breast cancer. Finally, we are gearing up to initiate a registration strategy for niraparib in metastatic non-small cell lung cancer. Lung cancer is of particular interest because a large number of these patients have reduced expression of genes involved in DNA repair pathways and a high rate of homologous recombination deficiency, both hallmarks of sensitivity to PARP inhibition. A Phase 2 trial will begin in the next several months to assess the combination of niraparib and an anti-PD-1 antibody in patients with metastatic non-small cell lung cancer patients regardless of PD-L1 tumor expression. Data from this study will inform us as to the optimal population for inclusion in the Phase 3, which is currently planned to enroll patients with high PD-L1 expression.

In addition to anti-PD-1 we are assessing the potential of a niraparib combination with bevacizumab.

SLIDE 14 — POTENTIAL TO COMBINE WITH BEV

The AVANOVA study, which is being conducted by our ENGOT collaborators, is evaluating the combination of niraparib plus bevacizumab in patients with recurrent ovarian cancer. Initial promising data were reported at ASCO and led to expansion in the ongoing phase 2 portion of the study in which patients are randomized to niraparib versus niraparib plus bevacizumab. We expect to report updated data from the AVANOVA study at a medical meeting in the second half of 2017.

SLIDE 15 — PIPELINE UPDATE, VARUBI/Y

Turning to VARUBI. As Lonnie mentioned, we are excited to have received approval of VARUBY oral by the European Commission—marking our first international approval—and we look forward to bringing this important product to patients in Europe beginning late in the second quarter. Importantly, we recently re-submitted the NDA for VARUBI IV, and pending FDA approval, expect to launch VARUBI IV in mid-2017. These are important regulatory achievements for TESARO and I am deeply grateful for the hours of work that our teams have provided in support of these products.

SLIDE 16 — I-O PORTFOLIO

Finally, our immuno-oncology programs. We believe, as do many, that combination immuno-oncology treatments that include antibodies directed to PD-1, TIM-3 and LAG-3, could become a foundation of cancer therapy regimens across a variety of tumor types. Having these three antibodies in our pipeline provides a competitive advantage, and allows TESARO to be well positioned to collaborate with others who may have complementary approaches.

A phase 1 trial of our TSR-042 anti-PD-1 antibody is enrolling patients in the cohort expansion phase which will form the basis for a registrational development program in metastatic, MSI-high endometrial cancer. This study is designed to support Biologics License Application or BLA submission to the FDA and request for accelerated approval.

Additionally, enrollment is ongoing in the dose escalation stage of our phase 1 study of TSR-022, our anti-TIM-3 antibody, and a combination trial of TSR-022 plus TSR-042, is planned to initiate mid-year. Finally, we recently submitted an IND for TSR-033, our anti-LAG-3 clinical candidate, and we are preparing to initiate a Phase 1 clinical trial towards this summer.

As our clinical data package expands and the potential value of combination studies with niraparib and our three I-O antibodies also grows, we will look forward to sharing with you during what promises to be a very exciting year for our patients, our shareholders, and all of us here at TESARO.

With that, I'll turn the call back to Lonnie.

SLIDE 17 — LONNIE'S TITLE SLIDE

I'll now turn the call back over to Lonnie. Lonnie?

LONNIE:

SLIDE 18 — CORPORATE GOALS

Thanks, Mary Lynne.

In summary, we are extremely pleased with the initial ZEJULA launch and our progress so far this year. I'll wrap up with a brief summary of our goals for this year.

We plan to launch three more products in 2017, including VARUBY oral in Europe, VARUBI IV in the US, and ZEJULA in Europe. We anticipate multiple niraparib data readouts, including TOPACIO data at our ASCO IR event and at a medical meeting later this fall, plus QUADRA and AVANOVA data in the second half of the year. Our I-O portfolio will continue to advance as we initiate the registration program for TSR-042 in metastatic endometrial cancer, begin to combine TSR-042 and TSR-022, and advance TSR-033 into the clinic.

SLIDE 19 — Q&A

Operator, at this point, could we please open the call for questions?

(Q&A…)

JEN:

Operator, we will take one final question.

OPERATOR:

Thank you. I will now turn the call back over to Lonnie Moulder.

SLIDE 20: CLOSING TITLE SLIDE

LONNIE:

We appreciate your interest in TESARO. Thank you everyone, and have a good evening.

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.

Forward Looking Statements

To the extent that statements contained in this document 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 document include, among others, statements regarding the expected timing of the launch of VARUBI IV in the U.S., the expected timing of our planned commercial launches of ZEJULA and VARUBY in Europe, the expected approval of the rolapitant IV NDA and the timing thereof, the design and expected timing of our various planned niraparib, planned TSR-042, TSR-033, TSR-022, combination studies, and other ongoing clinical trials, our projected cash utilization during the second quarter of 2017, and our expectation to achieve our various key corporate objectives. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our research and pre-clinical development programs, 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 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.