TESARO, INC.

FORM 8-K
(Current report filing)

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Address	1000 WINTER STREET, SUITE 3300 WALTHAM, MA 02451
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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): **January 11, 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** (Address of principal executive offices)	**02451** (Zip Code)	**(339) 970-0900** (Registrant's telephone number, including area code)

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))

Item 8.01 Other Events.

On January 11, 2017, TESARO, Inc. (the "Company") received a complete response letter (the "CRL") from the U.S. Food and Drug Administration ("FDA") with respect to the New Drug Application for the intravenous formulation of rolapitant for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy. In the CRL, FDA requested additional information regarding the *in vitro* method utilized to demonstrate comparability of drug product produced at the two different proposed commercial manufacturers for rolapitant IV emulsion that were included in the NDA. The press release announcing receipt of the CRL is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of the Company dated January 11, 2017 announcing receipt of a Complete Response Letter with respect to the NDA for the intravenous formulation of rolapitant.

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: January 12, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of the Company dated January 11, 2017 announcing receipt of a Complete Response Letter with respect to the NDA for the intravenous formulation of rolapitant.

FOR RELEASE ON JANUARY 11, 2017

TESARO RECEIVES COMPLETE RESPONSE LETTER FOR ROLAPITANT IV FROM U.S. FDA

- **No concerns raised by FDA related to the rolapitant IV efficacy or safety profile and additional clinical studies are not required**
- **Investor conference call and webcast scheduled for tomorrow at 8:30AM ET**

WALTHAM, MA, January 11, 2017 — TESARO, Inc. (NASDAQ: TSRO), an oncology-focused biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the rolapitant IV New Drug Application (NDA) for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy.

FDA requested additional information regarding the *in vitro* method utilized to demonstrate comparability of drug product produced at the two proposed commercial manufacturers for rolapitant IV that were included in the NDA. TESARO is working expeditiously to provide the requested information.

The CRL did not identify concerns related to the safety or efficacy of rolapitant IV or request additional clinical studies. No concerns were raised regarding the active pharmaceutical ingredient (API), which is also used for the VARUBI® (rolapitant) oral product.

TESARO identified potential deficiencies at the original contract manufacturer for rolapitant IV drug product, secured a second drug product supplier and included data from this manufacturer in the NDA. During the NDA review, FDA requested and TESARO provided *in vitro* data to demonstrate comparability of drug product made at the two manufacturing sites

“Chemotherapy-induced nausea and vomiting (CINV) remains a significant unmet need, with more than half of patients treated with emetogenic chemotherapy experiencing this debilitating side effect,” said Mary Lynne Hedley, Ph.D., President and COO of TESARO. “TESARO is committed to bringing this new intravenous formulation of rolapitant to physicians and patients to enable additional flexibility and choice of antiemetic regimens, and we plan to address FDA’s questions expeditiously and complete this application, which we expect to enable approval in the first half of 2017.”

Investor Conference Call and Webcast

TESARO will host a conference call to discuss this announcement tomorrow, January 12, at 8:30 A.M. Eastern time. The live webcast of the conference call can be accessed by visiting the TESARO website at www.tesarobio.com. The call can be accessed by dialing (877) 853-5334 (U.S. and Canada) or (970) 315-0307 (international). A replay of the webcast will be archived on the Company’s website for 30 days following the call .

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 www.varubirx.com.

TESARO licensed exclusive rights for the development, manufacture, commercialization and distribution of VARUBI (rolapitant) from OPKO Health, Inc.

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.

Investor/Media Contact:

Jennifer Davis
Sr. Director, Corporate Development & 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 TESARO's plans to meet with FDA, provide the data requested in the complete response letter, bring the IV formulation of rolapitant to physicians and patients, and our expectation that our response to the complete response letter will enable approval of rolapitant IV in the first half of 2017 without additional clinical studies. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our future results, performance, or achievements, including the potential approval and launch of the IV formulation of rolapitant, to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in drug development and the execution and completion of clinical trials, uncertainties surrounding our ongoing discussions with and potential actions by the FDA, uncertainties regarding the ultimate regulatory approval of the IV formulation of rolapitant, risks related to manufacturing and supply of the IV formulation of rolapitant, and other matters that could affect the ultimate approval, availability or commercial potential of the IV formulation of rolapitant. 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, 2015, and Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.

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