TESARO, Inc.
Form 8-K
January 12, 2017

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 8-K

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**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**

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# 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** | **(339) 970-0900** |
| (Address of principal executive offices) | (Zip Code) | (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):

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))

**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**

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