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 12, 2018**

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**

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:

☐ 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 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.

On January 12, 2018, TESARO, Inc. issued a press release announcing updates to the U.S. prescribing information for VARUBI® (rolapitant) injectable emulsion. 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	Press release of TESARO, Inc. dated January 12, 2018 announcing updates to the U.S. prescribing information for VARUBI injectable emulsion.

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 16, 2018

Exhibit 99.1

TESARO Announces Updates to the U.S. Prescribing Information for VARUBI® (rolapitant) Injectable Emulsion

WALTHAM, Mass., Jan. 12, 2018 — TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that it has updated the VARUBI® (rolapitant) injectable emulsion package insert in collaboration with the U.S. Food and Drug Administration (FDA). VARUBI injectable emulsion is a substance P/neurokinin (NK-1) receptor antagonist indicated for the prevention of delayed nausea and vomiting associated with chemotherapy in adults. The changes to the labeling include modifications to the CONTRAINDICATIONS, WARNINGS and PRECAUTIONS, and ADVERSE REACTIONS sections.

Following its introduction in late November 2017, TESARO estimates that at least 7,000 doses of VARUBI injectable emulsion have been administered to patients receiving emetogenic chemotherapy in the United States. Anaphylaxis, anaphylactic shock and other serious hypersensitivity reactions have been reported in the postmarketing setting, some requiring hospitalization. These reactions have occurred during or soon after the infusion of VARUBI injectable emulsion. Most reactions have occurred within the first few minutes of administration.

Patient safety is a paramount priority for TESARO. In its commitment to ensuring patients and healthcare professionals are aware of the label update, TESARO has issued a Dear Healthcare Professional (DHCP) letter. This letter, as well as the updated full prescribing information, has been posted on the VARUBI website (www.varubirx.com). Additionally, members of the TESARO field force will be calling on healthcare professionals to communicate this important new safety information.

Healthcare providers and patients are encouraged to report adverse events in patients taking VARUBI injectable emulsion to TESARO at 1-844-4-TESARO (1-844-483-7276). TESARO's medical information department may be reached at 1-844-4-TESARO (1-844-483-7276) to address any questions from healthcare providers about the information contained in this release, or the safe and effective use of VARUBI injectable emulsion.

VARUBI Indication and Important Safety Information

VARUBI, in combination with other antiemetic agents, is indicated 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.

VARUBI is contraindicated in patients taking CYP2D6 substrates with a narrow therapeutic index, such as thioridazine and pimozide. VARUBI can significantly increase the plasma concentrations of thioridazine and pimozide, which may result in QT prolongation and Torsades de Pointes.

VARUBI is a moderate inhibitor of CYP2D6 and significantly increases the plasma concentrations of CYP2D6 substrates for at least 28 days, with inhibitory effects expected to persist for an unknown duration. Monitor for adverse reactions when VARUBI is coadministered with CYP2D6 substrates without a narrow therapeutic index (avoid coadministration with CYP2D6 substrates with a narrow therapeutic index, thioridazine and pimozide; see Contraindication).

In clinical trials, the most common adverse reactions reported were neutropenia, hiccups, decreased appetite and dizziness. IV administration of VARUBI was also associated with infusion-related symptoms (e.g., sensation of warmth, abdominal pain, dizziness, and paresthesia).

Avoid use of VARUBI in patients who require chronic administration of strong CYP3A4 inducers (e.g., rifampin), as significantly reduced plasma concentrations of VARUBI can decrease the efficacy of VARUBI.

VARUBI given as an oral dose is an inhibitor of breast cancer resistance protein (BCRP) and P-glycoprotein (P-gp). Increased plasma concentrations of BCRP substrates (e.g., methotrexate, topotecan, or irinotecan) and P-gp substrates (e.g., digoxin) with a narrow therapeutic index may result in potential adverse reactions. Monitor digoxin concentrations with concomitant use of VARUBI, and adjust the dosage as needed to maintain therapeutic concentrations.

Monitor INR and prothrombin time and adjust the dosage of warfarin, as needed, to maintain target INR.

VARUBI is available by prescription only. Please see full prescribing information, including additional important safety information, available at www.varubirx.com.

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

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Forward Looking Statement

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, estimates 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 such forward-looking statements. For example, the information in this press release relating to the Company's estimate of the number of doses of VARUBI® injectable emulsion administered is a forward-looking statement reflecting the current belief and best estimate of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This statement and other forward-looking statements contained herein involve substantial risks and uncertainties including, among others, risks and uncertainties associated with the completion of the integrated audit of the Company's financial statements for the year ended December 31, 2017 and the quarter ending March 31, 2018. Our estimate of the number of doses of VARUBI® injectable emulsion administered should not be used to extrapolate or estimate potential revenues from sales of VARUBI injectable emulsion for such periods, as the determination of such revenues is subject to a number of risks, uncertainties, and estimates which are unknown, including estimates of product returns. Accordingly, any estimates of revenues for such period would be highly speculative and unreliable. TESARO undertakes no obligation to update or revise any such forward-looking statements. For a further description of the risks and uncertainties 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 its Quarterly Report on Form 10-Q for the quarter ended September 30, 2017.