# TESARO, INC.

## FORM 8-K
(Current report filing)

Filed 07/27/17 for the Period Ending 07/27/17

| | |
|---|---|
| Address | 1000 WINTER STREET, SUITE 3300<br>WALTHAM, MA 02451 |
| Telephone | (339) 970-0900 |
| CIK | 0001491576 |
| Symbol | TSRO |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

# 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): **July 27, 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**<br>**Suite 3300**<br>**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)

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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 1 — Registrant's Business and Operations**

**Item 1.01 Entry Into a Material Definitive Agreement.**

On July 27, 2017, TESARO, Inc. (the "Company") entered into an Exclusive License Agreement (the "Agreement") with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda").

Under the terms of the Agreement, the Company granted Takeda an exclusive, sublicensable license to develop, manufacture and commercialize niraparib, the Company's novel poly (ADP-ribose) polymerase, or PARP, inhibitor in Japan, South Korea, Taiwan, Russia and Australia (the "Licensed Territory"). The licensed field in Japan is the treatment of all diseases in humans and the licensed field in South Korea, Taiwan, Russia and Australia is the treatment of all diseases in humans other than prostate cancer. In partial consideration for the license granted to Takeda, Takeda will pay the Company an up-front license fee in the amount of $100,000,000, certain development and commercial milestone payments in amounts up to an aggregate of $240,000,000, and royalties based on percentages of net sales of niraparib in the Licensed Territory ranging from the high-teens to the low thirties, with the Company retaining payment obligations for any milestones and royalties owed under its existing in-license agreements for niraparib.

Also under the terms of the Agreement, Takeda granted the Company a perpetual, non-exclusive license to any intellectual property covering niraparib owned or controlled by Takeda, to the extent necessary or useful to develop, manufacture and commercialize niraparib for use outside the Licensed Territory.

The Agreement also provides that the Company and Takeda will enter into supply agreements for the clinical and commercial supply of the active pharmaceutical ingredient of the product and the product.

The Agreement is effective from and after July 27, 2017, and continues, on a country-by-country and product-by-product basis, until the expiration of the last patent controlled by the Company in such country covering the niraparib product or, if later, ten years from the first commercial sale of such niraparib product in such country.

The Agreement may be terminated by either party if the other party commits a material breach, subject to a customary cure period, or if the other party is insolvent. Additionally, the Company may terminate the Agreement in the event of certain patent challenges against the Company's patents covering niraparib, if the Company's in-license agreements to niraparib terminate due to any action or inaction of Takeda and, with respect to Japan, with three months' notice any time after the 18 month anniversary of the first commercial sale of a generic version of the niraparib product in Japan. Takeda may terminate the Agreement for convenience on a country-by-country basis upon 180 days' prior notice to the Company.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the Agreement, a copy of which the Company intends to file as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2017.

**Section 7 — Regulation FD**

**Item 7.01 Regulation FD Disclosure.**

On July 27, 2017, the Company issued a press release announcing entrance into the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Section 9 — Financial Statements and Exhibits**

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | TESARO, Inc. press release dated July 27, 2017 announcing Exclusive License Agreement with Millennium Pharmaceuticals, Inc. |

**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: July 27, 2017

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | TESARO, Inc. press release dated July 27, 2017 announcing Exclusive License Agreement with Millennium Pharmaceuticals, Inc. |

**TESARO AND TAKEDA ENTER INTO EXCLUSIVE LICENSING AGREEMENT TO DEVELOP AND COMMERCIALIZE NOVEL CANCER THERAPY NIRAPARIB IN JAPAN**

***— Takeda's Rights Include all Potential Indications for Niraparib in Japan and Rights Excluding Prostate Cancer in South Korea, Taiwan, Russia and Australia***

***— TESARO to Receive $ 100 Million Upfront Payment and is Eligible for Future Regulatory and Commercial Milestones, Plus Royalties***

**Waltham, MA, U.S. and Osaka, Japan — J uly 27 , 201 7 —** TESARO, Inc. (NASDAQ: TSRO) and Takeda Pharmaceutical Company Limited (TSE:4502) today announced an exclusive licensing agreement for the commercialization and clinical development of niraparib, a novel poly ADP-ribose polymerase (PARP) inhibitor. This agreement includes the development of niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea, Taiwan, Russia and Australia. Niraparib, first marketed in the U.S. in April under the brand name ZEJULA™, has quickly become the most frequently prescribed PARP inhibitor in the U.S.

Under the terms of this agreement, TESARO will receive a $100 million upfront payment and is eligible to receive additional milestone payments of up to $240 million related to the achievement of certain regulatory and commercial goals. TESARO will also be eligible to receive from Takeda tiered royalties based on a double digit percentage of net product sales. Takeda gains exclusive commercial rights for all potential future niraparib indications in Japan, and rights excluding prostate cancer in South Korea, Taiwan, Russia and Australia. Takeda will be responsible for development of niraparib in Japan and the four specified countries, including all associated expenses. Additional terms of this agreement were not disclosed.

"The niraparib development program addresses many of the most prevalent and devastating cancers worldwide. We must continue to make new treatments available to patients and, through research, further our knowledge into the full utility of this molecule," said Christophe Bianchi, President of Takeda Oncology.

"We are pleased to be collaborating with TESARO, a company we admire for its high caliber oncology expertise. This agreement represents another step in our goal of building Takeda's robust portfolio in solid tumors and, more importantly, our commitment to patients living with cancer who desperately want — and need — new, innovative therapies."

Once-daily niraparib is the first and only PARP inhibitor that has received approval for the maintenance treatment of women with recurrent ovarian cancer, regardless of *BRCA* mutation or biomarker status. TESARO's development plan currently includes clinical trials of niraparib in patients with ovarian, breast, and lung cancer. Janssen Biotech has licensed rights to develop and commercialize niraparib specifically for patients with prostate cancer worldwide, except in Japan.

"TESARO is devoted to providing transformative therapies for people bravely facing cancer, and this partnership enables us to continue to globalize our mission," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "As the largest pharmaceutical company in Japan, Takeda is recognized as a leader in oncology, and we are excited to work with the Takeda team to quickly advance niraparib for patients who are in need of new treatment options."

Niraparib is not currently approved for use in Japan, South Korea, Russia, Taiwan or Australia.

**About ZEJULA (Niraparib)**

ZEJULA (niraparib) is a poly(ADP-ribose) polymerase (PARP) inhibitor indicated 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. Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including some fatal cases, was reported in patients treated with ZEJULA. Discontinue ZEJULA if MDS/AML is confirmed. Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia), as well as cardiovascular effects (hypertension and hypertensive crisis) have been reported in patients treated with ZEJULA. Monitor complete blood counts to detect hematologic adverse reactions, as well as to detect cardiovascular disorders, during treatment. ZEJULA can cause fetal harm and females of reproductive potential should use effective contraception. Please see full prescribing information, including additional important safety information, available at www.zejula.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 .

**About Takeda Pharmaceutical Company**

Takeda Pharmaceutical Company Limited is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and central nervous system therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as our presence in Emerging Markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

Additional information about Takeda is available through its corporate website, www.takeda.com, and additional information about Takeda Oncology, the brand for the global oncology business unit of Takeda Pharmaceutical Company Limited, is available through its website, www.takedaoncology.com\

**TESARO 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. 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, risks associated with competition in the PARP market, risks related to pricing and reimbursement, risks related to manufacturing and supply, risks related to intellectual property, and other risks and uncertainties that could affect the availability or commercial potential of niraparib in Japan, South Korea, Australia, Taiwan and Russia. 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.*

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**TESARO Contact**

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