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): **November 1, 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**

(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 November 1, 2018, TESARO, Inc. (the "Company") issued a press release announcing its operating results for the quarter ended September 30, 2018 and providing updated revenue, expense, cash balance, and other financial guidance for the year ending December 31, 2018. A copy of the press release is attached to this current report as Exhibit 99.1 and is incorporated herein by reference. TESARO, Inc. has scheduled a conference call and webcast for 4:15 p.m. Eastern time on November 1, 2018 to discuss its operating results for the quarter ended September 30, 2018 and provide an update on the Company's commercial products and development programs.

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	TESARO, Inc. press release dated November 1, 2018 announcing operating results for the quarter ended September 30, 2018.

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: November 1, 2018

Exhibit 99.1

TESARO ANNOUNCES THIRD-QUARTER 2018 OPERATING RESULTS

- **ZEJULA® Q3 net sales totaled $63 million compared to $39 million for Q3 2017**
- **Top-line results for PRIMA trial of ZEJULA monotherapy for first-line ovarian cancer patients regardless of BRCA mutation status anticipated in late 2019**
- **Data presented at ESMO for TSR-042 indicate robust activity in patients with MSI-high endometrial cancer; TSR-042 BLA submission planned for 2H 2019**

WALTHAM, Mass., November 1, 2018 — TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today reported operating results for third-quarter 2018 and provided an update on the Company's commercial products and development programs.

"In the third quarter, we launched several initiatives to grow the use of ZEJULA for recurrent ovarian cancer and we continued to execute on our development strategies focused on gynecologic and lung cancers as we approach a period of significant data readouts," said Lonnie Moulder, CEO of TESARO. "Following results of the Phase 3 PRIMA trial next year, we intend for ZEJULA to benefit patients throughout all stages of their ovarian cancer journey, including first-line, recurrent, and late-line treatment settings. Our immuno-oncology pipeline continues to advance, led by our anti-PD-1 antibody, TSR-042, for which we are on track to submit a BLA next year. We look forward to initial data from the Phase 1 AMBER trial of our anti-TIM-3 antibody, TSR-022, in combination with TSR-042, which will be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting next week."

Recent Business Highlights

- ZEJULA net revenue increased 61% year-over-year to $63.2 million for the third quarter of 2018. In the U.S. and Europe, approximately 10,000 patients have been treated with ZEJULA since its launch in April 2017. ZEJULA is now approved in 33 countries and is reimbursed and launched in Germany, the U.K., Italy and several other European countries.
- Safety data were presented from the Phase 3 PRIMA trial of ZEJULA monotherapy in first-line ovarian cancer during the European Society for Medical Oncology (ESMO) Annual Congress in October. Data demonstrated a favorable tolerability profile for niraparib when dosed according to a patient's weight and platelet count compared to a fixed starting dose. The PRIMA Phase 3 trial is fully enrolled and top-line results are expected in late 2019.
- Based upon the responses observed in the first stage of the study, the second stage of the Phase 2 JASPER study was initiated, which evaluates ZEJULA in combination with TSR-042 as a first-line treatment for patients with non-small cell lung cancer and high levels of PD-L1 expression.
- Data were presented from the GARNET trial of TSR-042 monotherapy at ESMO and demonstrated TSR-042 is well tolerated and has robust clinical activity in patients with MSI-H endometrial cancer.
- Zai Lab Limited announced ZEJULA approval in Hong Kong on October 22, 2018. ZEJULA is the first and only PARP inhibitor approved in Hong Kong for the maintenance treatment of platinum-sensitive relapsed ovarian cancer regardless of *BRCA* mutation status.

- In October, TESARO and actress Cobie Smulders launched *Not on My Watch*, a national movement to empower the ovarian cancer community, especially women with recurrent ovarian cancer, to take informed and proactive steps against the threat of disease recurrence.
- Development milestones were achieved in October related to Janssen's ongoing GALAHAD trial of niraparib monotherapy for the treatment of men with metastatic castration-resistant prostate cancer (mCRPC) and DNA-repair anomalies. The achievement of these milestones triggered an $18 million payment from Janssen to TESARO.

Third Quarter 2018 Financial Results

TESARO reported net product revenue of $63.6 million for the third quarter of 2018, compared to a total of $41.8 million for the third quarter of 2017. ZEJULA net revenue increased 61% to $63.2 million for the third quarter of 2018, compared to $39.4 million for the third quarter of 2017. Cost of goods sold increased to $14.2 million for the third quarter of 2018, compared to $6.2 million for the same period in 2017, primarily related to increased volume and new supplier set-up expenses.

Research and development expenses increased to $94.2 million for the third quarter of 2018, compared to $73.4 million for the third quarter of 2017, driven primarily by higher manufacturing and clinical development costs associated with TSR-042, TSR-022, and ZEJULA, and research collaborations.

Selling, general and administrative expenses increased to $93.5 million for the third quarter of 2018, compared to $84.0 million for the third quarter of 2017, primarily due to increased headcount and activities in support of the launches of ZEJULA in the U.S. and Europe.

Operating expenses as described above include total non-cash, stock-based compensation expense of $24.8 million for the third quarter of 2018, compared to $25.0 million for the third quarter of 2017.

Net loss totaled $137.1 million, or ($2.49) per share, for the third quarter of 2018, compared to a net loss of $25.3 million, or ($0.47) per share, for the third quarter of 2017. The increase in net loss was primarily due to the $100.0 million up-front payment received and recorded as revenue in the third quarter of 2017 as part of the license agreement with Takeda, partially offset by a $17.6 million gain in the third quarter of 2018 associated with the divestiture of VARUBI in the U.S., for which TESARO received an up-front payment of $35 million.

(in thousands, except per share amounts)	Three Months Ended September 30, 2018	2017
Product revenue, net		
ZEJULA®	$ 63,226	$ 39,375
VARUBI®/VARUBY®	$ 386	$ 2,380
Total product revenue, net	$ 63,612	$ 41,755
License, collaboration, and other revenue	$ 787	$ 101,011
Total revenues	$ 64,399	$ 142,766
Net loss	$ (137,088)	$ (25,277)
Net loss per share, basic and diluted	$ (2.49)	$ (0.47)

(in thousands)	Three Months Ended September 30, 2018	2017
Cost of sales - product	$ 14,225	$ 6,216
Cost of sales - intangible asset amortization	$ 728	$ 1,254
Research and development (R&D)	$ 94,188	$ 73,388
Selling, general and administrative (SG&A)	$ 93,497	$ 83,998
Acquired in-process R&D	$ —	$ —

Cash and Cash Equivalents

As of September 30, 2018, TESARO had approximately $476.8 million in cash and cash equivalents and approximately 55.0 million outstanding shares of common stock.

2018 Financial Guidance

TESARO is updating its 2018 financial guidance for ZEJULA:

Total Revenue, net, worldwide (FY)	$258 to $265 million (previously $250 to $265 million)
ZEJULA (FY)	$233 to $238 million (previously $225 to $235 million)
ZEJULA (Q4)	$67 to $72 million
Other revenue, including licensing and VARUBY oral (FY)	$25 to $27 million (previously $25 to $30 million)
Interest expense (FY)	Approximately $60 million, including non-cash interest expense of $14 million

In the third quarter, TESARO's cash and cash equivalents balance declined by approximately $98 million. TESARO anticipates year-end 2018 cash and cash equivalents to be approximately $400 million.

Key Development Milestones

Gynecologic Cancers:

- Submit QUADRA sNDA for treatment of late-line ovarian cancer beyond *BRCA*mut near year-end
- Results of the AVANOVA Phase 2 study of ZEJULA in combination with bevacizumab for treatment of recurrent ovarian cancer to be submitted for presentation at a medical meeting in 1H 2019
- Report Phase 2 OVARIO results of ZEJULA in combination with bevacizumab in first-line ovarian cancer maintenance in late 2019
- Report Phase 3 PRIMA results of ZEJULA in first-line ovarian cancer maintenance in late 2019

Lung Cancer:

- Report initial data for the AMBER trial of TSR-022 in combination with TSR-042 at the Society for Immunotherapy of Cancer's (SITC) Annual Meeting on November 9
- Report additional data from the NSCLC cohort of the GARNET trial of TSR-042 at SITC
- Initiate Phase 2 registration enabling trial of TSR-042 versus standard of care in first-line NSCLC in early 2019
- Report additional data from the Phase 2 JASPER study of ZEJULA in combination with anti-PD-1 at a medical meeting in 1H 2019

Breast Cancer:

- Submit BRAVO data for ZEJULA in germline *BRCA*mut breast cancer patients for publication in Q4 2018
- Complete protocol development for registration study of ZEJULA in combination with TSR-042 and other agents in breast cancer

Prostate Cancer:

- Janssen to advance GALAHAD trial of ZEJULA in mCRPC and DNA-repair anomalies to support global regulatory filings in 2019
- Planning underway by Janssen for a future Phase 3 trial that will assess the clinical benefit of niraparib in combination with abiraterone acetate + prednisone in mCRPC patients

Immuno-oncology Pipeline:

- Continue dose-escalation in the CITRINO trial (combination of TSR-033 plus TSR-042) and report Phase 1 monotherapy dose-escalation data for TSR-033 at SITC
- Advance IND-enabling studies of PD-1/LAG-3 bi-specific antibody (TSR-075)

Today's Conference Call and Webcast

TESARO will host a conference call to discuss the Company's third quarter operating results and provide an update on the Company's commercial products and development programs today at 4:15 P.M. Eastern time. The accompanying slide presentation and 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 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.

Investor/Media Contact:
Kate Rausch
Director, Investor Relations
1.781.257.2505
krausch@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: our 2018 revenue, interest expense, and cash balance guidance; the design and expected timing of initiation, enrollment, and data readouts and publications from our various ongoing and planned ZEJULA, TSR-042, TSR-033, TSR-022, combination, and other clinical trials; the expected timing of our various BLA, sNDA and other regulatory filings; and our expectation to achieve our various development milestones. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our research and development programs, future financial and other 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 related to the acceptance of our products in the marketplace, competition, the uncertainties inherent in the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from clinical trials, uncertainties surrounding potential actions by regulatory authorities, uncertainties regarding the expected timing and magnitude of certain expenditures, risks related to manufacturing and supply, risks related to intellectual property, the terms of our term loan facility, other matters that could affect our financial results, the results of our ongoing and planned development programs, and/or the availability or commercial potential of our products and 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, 2017 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2018.

TESARO, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product revenue, net:				
ZEJULA®	$ 63,226	$ 39,375	$ 165,989	$ 65,321
VARUBI®/VARUBY®	386	2,380	4,323	7,402
Total product revenue, net	63,612	41,755	170,312	72,723
License, collaboration and other revenues	787	101,011	1,037	102,580
Total revenues	64,399	142,766	171,349	175,303
Expenses:				
Cost of sales - product	14,225	6,216	37,735	10,280
Cost of sales - intangible asset amortization	728	1,254	3,663	4,723
Research and development (1)	94,188	73,388	288,551	210,910
Selling, general and administrative (1)	93,497	83,998	287,137	246,239
Acquired in-process research and development	—	—	—	7,000
Total expenses	202,638	164,856	617,086	479,152
Loss from operations	(138,239)	(22,090)	(445,737)	(303,849)
Gain on sale of business	17,627	—	17,627	—
Interest and other income (expense), net	(16,154)	(3,048)	(37,715)	(9,941)
Loss before income taxes	(136,766)	(25,138)	(465,825)	(313,790)
Provision for income taxes	322	139	730	271
Net loss	$ (137,088)	$ (25,277)	$ (466,555)	$ (314,061)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.49)	$ (0.47)	$ (8.51)	$ (5.82)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	54,957	54,241	54,807	53,971

(1) Expenses include the following amounts of non-cash stock-based compensation expense:

Research and development	$ 7,128	$ 8,545	$ 23,137	$ 23,532
Selling, general and administrative	17,630	16,471	56,158	43,393

TESARO, Inc.
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 476,812	$ 643,095
Accounts receivable	31,362	53,416
Inventories	108,822	57,939
Other current assets	31,382	33,511
Total current assets	648,378	787,961
Intangible assets, net	35,897	56,384
Property and equipment, net	9,923	9,652
Restricted cash	8,610	2,552
Other assets	8,032	5,636
Total assets	$ 710,840	$ 862,185
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 28,160	$ 4,172
Accrued expenses	150,933	154,808
Deferred revenue, current	530	324
Other current liabilities	10,819	6,902
Total current liabilities	190,442	166,206
Convertible notes, net	153,057	143,446
Long-term debt, net	490,525	293,659
Deferred revenue, non-current	141	211
Other non-current liabilities	7,467	9,577
Total liabilities	841,632	613,099
Total stockholders' equity (deficit)	(130,792)	249,086
Total liabilities and stockholders' equity (deficit)	$ 710,840	$ 862,185

###