TESARO Announces Fourth-Quarter and Full-Year 2017 Operating Results

February 27, 2018

- **ZEJULA is the #1 PARP inhibitor for women with ovarian cancer in the U.S.**
- **2017 ZEJULA® net sales totaled $109 million during first nine months of commercial launch**
- **Focused clinical development program for niraparib in ovarian cancer is advancing in first-line and platinum-resistant settings**
- **Multiple immuno-oncology clinical studies to read out in 2018**
- **Enrollment of registration trial of TSR-042 (anti-PD-1 mAb) to complete by YE 2018**

WALTHAM, Mass., Feb. 27, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today reported operating results for fourth-quarter and full-year 2017, and provided an update on the Company's commercial products and development programs.

“Following its April 2017 introduction in the U.S., ZEJULA quickly became the market-leading PARP inhibitor for women with ovarian cancer, and in the second half of 2017, six out of ten ovarian cancer patients who were treated with a PARP inhibitor received ZEJULA,” said Lonnie Moulder, CEO of TESARO. “Additionally, we are expanding the ZEJULA franchise with our ongoing launches in Europe and a focused clinical development program that utilizes both monotherapy and combination approaches to potentially further lengthen the time women with ovarian cancer are free from disease progression. 2018 will be an exciting year for our immuno-oncology portfolio as we anticipate multiple data readouts, including response data for TSR-042, our anti-PD-1 antibody, in patients with lung cancer and MSI-high tumors, initial results from the combination of TSR-022, our anti-TIM-3 antibody and TSR-042, and initial data from TSR-033, our anti-LAG-3 antibody.”

Recent Business Highlights

- ZEJULA is the most utilized PARP inhibitor among patients with ovarian cancer in the U.S., with more than 4,000 patients treated in 2017.
- Following European Commission (E.C.) approval in November 2017, ZEJULA now has marketing authorization in 32 countries and is the first and only PARP inhibitor authorized for marketing in Europe for the maintenance treatment of patients with recurrent ovarian cancer, regardless of *BRCA* mutation status. ZEJULA has been launched in Germany and is available in the UK for private pay patients.
- TESARO has applied to include ZEJULA in the UK’s Cancer Drug Fund (CDF) and will continue to work closely with the National Institute for Health and Care Excellence (NICE) and the National Health Service (NHS) England on the ZEJULA CDF submission to make this important medicine available as quickly as possible for a broad population of women in the UK.
- The unit demand for VARUBI oral tablets increased 43% for Q4 2017 vs. Q4 2016, as the brand continues to penetrate the U.S. oral NK-1 market.
- In January 2018, the package insert for VARUBI IV was updated to include mention of new adverse events, including anaphylaxis, anaphylactic shock and other serious hypersensitivity reactions, which were reported in the post-marketing setting following its introduction in late November 2017. Given these dynamics, TESARO believes the market opportunity is more limited than previously anticipated, and will suspend distribution of VARUBI IV while continuing to support VARUBI oral tablets. The Company is considering strategic alternatives for the product, including out-licensing, and will re-direct Company resources in support of ZEJULA.
- Clinical trials of niraparib are ongoing to evaluate safety and efficacy in monotherapy and combination therapy for patients with ovarian, breast, and lung cancer:
    - PRIMA: Phase 3 trial for patients with first-line ovarian cancer will complete enrollment in Q2 2018
    - QUADRA: Registrational trial for patients with ovarian cancer who have received three or more prior lines of chemotherapy; top-line data will be available in Q1 and an abstract has been submitted to ASCO
    - TOPACIO: Phase 2 trial in combination with anti-PD-1 for patients with platinum-resistant ovarian cancer (data to be presented at SGO) or triple negative breast cancer (abstracts submitted to ASCO)
    - AVANOVA: Phase 2 trial in combination with bevacizumab for patients with recurrent ovarian cancer; data are anticipated to be available in 2H 2018 to support an abstract submission
    - Niraparib tablet: A study is ongoing to advance development of a tablet formulation of niraparib
    - OVARIO: Phase 2 assessing niraparib in combination with bevacizumab for patients with newly diagnosed ovarian cancer
- Janssen continues to advance development of niraparib in prostate cancer in monotherapy and combination therapy.
- Zai Lab is advancing the development of niraparib in patients with ovarian, breast and lung cancer in China, and Takeda has initiated development of niraparib in Japan.
- TSR-042 is in a registration trial (GARNET) for MSI-high tumors.
    - An abstract has been submitted to AACR that includes data from patients with lung and metastatic microsatellite instability-high (MSI-H) cancers
    - Data are being generated to support the use of TSR-042 in registration studies in multiple tumor types, including lung, breast and ovarian cancer
- Clinical trials are ongoing to evaluate TSR-022 (anti-TIM-3 antibody) and TSR-033 (anti-LAG-3 antibody) in combination with TSR-042.
    - AMBER: Phase 1 trial of TSR-022 in combination with TSR-042 is enrolling three tumor specific cohorts

    - CITRINO: Phase 1 dose-escalation trial of TSR-033
- A retrospective, exploratory analysis of the NOVA trial, presented as part of a Satellite Symposium at the International Meeting of the European Society of Gynaecological Oncology (ESGO) in November 2017 in Austria, identified body weight and baseline platelet counts as the two most significant predictors for grade 3/4 thrombocytopenia.
- In November, preliminary Phase 1 data presented at the 2017 Annual Meeting of the Society for Immunotherapy of Cancer (SITC) demonstrated TSR-022 is well tolerated across multiple dose levels, with a safety and efficacy profile expected for checkpoint inhibitors.
- TESARO entered into a definitive term loan agreement for up to $500 million with Pharmakon Advisors, LP in November 2017, and drew $300 million in December 2017.

2017 Financial Results

TESARO reported total revenue for the fourth quarter of 2017 of $48.0 million, compared to $4.9 million for the same period in 2016. Revenue growth was primarily driven by the launch of ZEJULA in the U.S. in April 2017. Net loss for the fourth quarter of 2017 totaled $182.1 million, or ($3.35) per share, compared to $136.2 million, or ($2.59) per share for the same period in 2016.

Full year 2017 total revenues were $223.3 million, compared to $58.0 million for 2016. Revenue growth was primarily driven by the launch of ZEJULA in the U.S. and the upfront payment received as part of the license agreement with Takeda in the third quarter. Net loss for 2017 totaled $496.1 million, or ($9.17) per share, compared to a net loss of $374.2 million, or ($7.85) per share, for 2016.

(in thousands, except per share amounts)	**Three Months Ended December 31,**		**Twelve Months Ended December 31,**	
	2016	**2017**	**2016**	**2017**
Product revenue, net				
ZEJULA®	-	$ 43,436	-	$ 108,756
VARUBI®/VARUBY®	$ 2,330	$ 4,541	$ 5,174	$ 11,944
Total product revenue, net	$ 2,330	$ 47,977	$ 5,174	$ 120,700
License, collaboration, and other revenue	$ 2,591	$ 46	$ 52,844	$ 102,626
Total revenues	$ 4,921	$ 48,023	$ 58,018	$ 223,326
Net loss	$ (136,240)	$ (182,065)	$ (374,224)	$ (496,126)
Net loss per share, basic and diluted	$ (2.59)	$ (3.35)	$ (7.85)	$ (9.17)

Product Revenue

Net product sales totaled $48.0 million for the fourth quarter of 2017, and included ZEJULA sales of $43.4 million and VARUBI/VARUBY sales of $4.5 million. This compares to net product sales of $2.3 million for the fourth quarter of 2016. The increase was primarily driven by the launch of ZEJULA in the U.S. in April 2017.

Net product sales for 2017 totaled $120.7 million and included ZEJULA sales of $108.8 million and VARUBI/Y sales of $11.9 million. For 2016, net product sales were $5.2 million.

Other Revenue

License, collaboration and other revenues for 2017 totaled $102.6 million and included the $100.0 million up-front payment received as part of the license agreement with Takeda in the third quarter. For 2016, license, collaboration, and other revenues were $52.8 million and included up-front payments received as part of the license agreements with Zai Lab and Janssen.

Operating Expenses

(in thousands)	**Three Months Ended December 31,**		**Twelve Months Ended December 31,**	
	2016	**2017**	**2016**	**2017**
Cost of sales - product	$ 512	$ 30,857	$ 1,203	$ 41,137
Cost of sales - intangible asset amortization	$ 464	$ 1,435	$ 1,855	$ 6,158
Research and development (R&D)	$ 71,514	$ 97,832	$ 235,144	$ 308,742
Selling, general and administrative (SG&A)	$ 54,526	$ 90,569	$ 158,578	$ 336,808
Acquired in-process R&D	$ 9,000	$ 3,000	$ 18,940	$ 10,000

For the fourth quarter of 2017, compared to the same period in 2016:

Cost of sales associated with product sales increased to $30.9 million compared to $0.5 million, primarily due to the commercial launch of ZEJULA in the U.S., and inventory write-downs and other charges of $20.3 million related to revised expectations for future VARUBI IV revenue.

Cost of sales associated with intangible asset amortization increased to $1.4 million compared to $0.5 million primarily due to the amortization of milestones recorded upon FDA and European Commission approval of ZEJULA and first commercial sale of VARUBY in Europe.

R&D expenses increased to $97.8 million compared to $71.5 million primarily due to higher manufacturing costs associated with TSR-042 and TSR-022, the expansion of the niraparib, TSR-042 and TSR-022 clinical development programs, and increased headcount.

SG&A expenses increased to $90.6 million compared to $54.5 million primarily due to increased sales and marketing headcount, activities in support of the launches of ZEJULA and VARUBI/Y in the U.S. and Europe, and higher professional service fees.

Acquired in-process R&D expenses totaled $3.0 million compared to $9.0 million and included a milestone payment related to our immuno-oncology portfolio.

Operating expenses include total non-cash, stock-based compensation expense of $23.5 million, compared to $14.4 million.

For full-year 2017, compared to 2016:

Cost of sales associated with product sales increased to $41.1 million compared to $1.2 million primarily due to the commercial launch of ZEJULA in the U.S., and inventory write-downs and other charges related to revised expectations for future VARUBI IV revenue.

Cost of sales associated with intangible asset amortization increased to $6.2 million compared to $1.9 million primarily due to the amortization of milestones recorded upon FDA and E.C. approvals of ZEJULA and first commercial sale of VARUBY in Europe.

R&D expenses increased to $308.7 million compared to $235.1 million due to increased headcount, higher manufacturing costs associated with TSR-042 and TSR-022, the expansion of the niraparib, TSR-042 and TSR-022 clinical development programs, and the advancement of our earlier-stage immuno-oncology portfolio.

SG&A expenses increased to $336.8 million compared to $158.6 million due to increased sales and marketing headcount, activities in support of the launches of ZEJULA and VARUBI/Y in the U.S. and Europe, and higher professional service fees.

Acquired in-process R&D expenses totaled $10.0 million and included milestone payments related to our immuno-oncology portfolio, compared to $18.9 million, which included milestone payments related to ZEJULA and our immuno-oncology portfolio.

Operating expenses include total non-cash, stock-based compensation expense of $90.4 million compared to $48.5 million.

Cash and Cash Equivalents

As of December 31, 2017, TESARO had approximately $643.1 million in cash and cash equivalents and approximately 54.5 million outstanding shares of common stock.

2018 Financial Guidance

In 2018, TESARO expects:

Total Revenue, net, worldwide (FY)	$310 to $345 million
ZEJULA (FY)	$255 to $275 million
ZEJULA (Q1)	$45 to $50 million
Other revenue, including licensing and VARUBI/Y oral (FY)	$55 to $70 million
Interest expense (FY)	$50 to $60 million, including non-cash interest expense of $14 million

In addition, TESARO anticipates its cash and cash equivalents balance to decline by $150 million during the first quarter. Quarterly declines in cash and cash equivalents are expected to moderate over the course of 2018, and in the fourth quarter of 2018, the decline in cash and cash equivalents balance is expected to be approximately $75 million. The Company plans to draw $200 million in 2018 from its available term loan facility. TESARO anticipates year-end 2018 cash and cash equivalents to be approximately $400 million.

Key Development Milestones

TESARO intends to achieve the following development milestones during 2018:

Ovarian Cancer Franchise:

- Complete PRIMA enrollment in Q2 2018
- Report TOPACIO platinum-resistant ovarian cancer data in 1H 2018
- Initiate FIRST, a Phase 3 clinical trial of niraparib in combination with TSR-042 in first-line ovarian cancer, in 1H 2018
- Report QUADRA data in 1H 2018 and submit sNDA in 2H 2018

Breast Cancer:

- Report TOPACIO triple negative breast cancer data in 1H 2018
- Publish BRAVO data in 2H 2018
- Define registration path for niraparib in breast cancer in mid-2018

Lung Cancer:

- Report initial data from lung cancer cohort of the GARNET trial of TSR-042 in NSCLC in 1H 2018
- Initial data from Phase 2 JASPER study of niraparib in combination with an anti-PD-1 inhibitor to be available in 2H 2018

Prostate Cancer:

- Janssen anticipates advancing trials of niraparib in prostate cancer to support U.S. and EU regulatory filings in 2019

Immuno-oncology Portfolio:

- Complete enrollment in the MSI-high cohort of the GARNET trial to support a BLA submission to FDA in 2019
- Report initial data for the AMBER trial of TSR-022 in combination with TSR-042 in 2H 2018 and define development strategy
- Initiate assessment of the combination of TSR-033 plus TSR-042 in the CITRINO trial in Q2 2018 and report Phase 1 monotherapy dose-escalation data for TSR-033 in 2H 2018
- Advance IND-enabling studies of PD-1/LAG-3 bi-specific (TSR-075)

Today's Conference Call and Webcast
TESARO will host a conference call to discuss fourth quarter and full-year operating results and provide an update on its 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.

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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 and interest expense guidance; statements regarding the expected decline in our cash and cash equivalents balance; statements regarding the design and expected timing of initiation, enrollment, and data from our various ongoing and planned niraparib, TSR-042, TSR-033, TSR-022, combination, and other clinical trials; and our expectation to achieve the Company's financial guidance for 2018 and our various key development milestones; and our intent to draw the remaining amount available under our term loan facility. 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, and 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, 2016, and Quarterly Report on Form 10-Q for the quarter ended September 30, 2017.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016 (as revised)(1)	2017	2016 (as revised)(1)	2017
Revenues:				
Product revenue, net:				
ZEJULA®	$ -	$ 43,436	$ -	$ 108,756
VARUBI®/VARUBY®	2,330	4,541	5,174	11,944
Total product revenue, net	2,330	47,977	5,174	120,700
License, collaboration and other revenues	2,591	46	52,844	102,626

Total revenues	4,921	48,023	58,018	223,326
Expenses:				
Cost of sales - product	512	30,857	1,203	41,137
Cost of sales - intangible asset amortization	464	1,435	1,855	6,158
Research and development (2)	71,514	97,832	235,144	308,742
Selling, general and administrative (2)	54,526	90,569	158,578	336,808
Acquired in-process research and development	9,000	3,000	18,940	10,000
Total expenses	136,016	223,693	415,720	702,845
Loss from operations	(131,095)	(175,670)	(357,702)	(479,519)
Interest and other income (expense), net	(3,670)	(5,342)	(15,047)	(15,283)
Loss before income taxes	(134,765)	(181,012)	(372,749)	(494,802)
Provision for income taxes	1,475	1,053	1,475	1,324
Net loss	$ (136,240)	$ (182,065)	$ (374,224)	$ (496,126)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.59)	$ (3.35)	$ (7.85)	$ (9.17)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	52,589	54,403	47,652	54,080

(1) The Company adopted Financial Accounting Standards Board Accounting Standards Update No. 2014-09 effective January 1, 2017, with full retrospective application to January 1, 2015. Results for periods prior to January 1, 2017 have been revised accordingly.

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

Research and development	$ 5,957	$ 7,278	$ 19,783	$ 30,810
Selling, general and administrative	8,434	16,223	28,672	59,616

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

	December 31, 2016 (as revised)(1)	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 785,877	$ 643,095
Accounts receivable	6,195	53,416
Inventories	14,700	57,939
Other current assets	10,515	33,511
Total current assets	817,287	787,961
Intangible assets, net	12,877	56,384
Property and equipment, net	6,640	9,652
Restricted cash	1,694	2,552
Other assets	3,795	5,636
Total assets	$ 842,293	$ 862,185
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,236	$ 4,172
Accrued expenses	68,700	154,808
Deferred revenue, current	95	324
Other current liabilities	2,978	6,902
Total current liabilities	77,009	166,206
Convertible notes, net	131,775	143,446

Long-term debt, net		-		293,659
Deferred revenue, non-current		305		211
Other non-current liabilities		5,086		9,577
Total liabilities		214,175		613,099
Total stockholders' equity		628,118		249,086
Total liabilities and stockholders' equity	$	842,293	$	862,185

(1) The Company adopted Financial Accounting Standards Board Accounting Standards Update No. 2014-09 effective January 1, 2017, with full retrospective application to January 1, 2015. Results for periods prior to January 1, 2017 have been revised accordingly.

Primary Logo

Source: TESARO, Inc.