TESARO Announces First-Quarter 2018 Operating Results

May 3, 2018

- **ZEJULA Q1 net sales totaled $49 million**
- **Enrollment completed in Phase 3 PRIMA first-line ovarian cancer monotherapy trial**
- **TOPACIO platinum-resistant ovarian cancer and triple-negative breast cancer data accepted for oral presentations at ASCO**
- **Initial data from two TSR-042 (anti-PD-1) GARNET expansion cohorts presented at AACR; regulatory submission for MSI-high tumors planned in 2019**

WALTHAM, Mass., May 03, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today reported operating results for first-quarter 2018, and provided an update on the Company's commercial products and development programs.

“2018 is off to an excellent start for TESARO, as ZEJULA continues to penetrate the recurrent ovarian cancer market,” said Lonnie Moulder, CEO of TESARO. “We expect to expand the market for ZEJULA to the front-line setting with PRIMA, our Phase 3 trial for patients with first-line ovarian cancer regardless of biomarker status, with data expected late next year. In March, data presented from our TOPACIO trial of ZEJULA in combination with an anti-PD-1 antibody surpassed historical monotherapy benchmarks in difficult-to-treat platinum-resistant and refractory ovarian cancer patients, and we look forward to presentations from both the ovarian and triple-negative breast cancer cohorts of TOPACIO at ASCO. Our immuno-oncology pipeline is advancing quickly and we are on track to submit a biologic license application for TSR-042, our anti-PD-1 antibody, for patients with MSI-high tumors in 2019. Enrollment continues in our AMBER trial of TSR-022, our anti-TIM-3 antibody, in combination with TSR-042, and data from this trial in tumor-specific expansion cohorts are expected to be presented at a medical meeting later this year.”

Recent Business Highlights

- ZEJULA is the most utilized PARP inhibitor among ovarian cancer patients in the U.S., with more than 5,000 patients treated since launch in April 2017. The European launch of ZEJULA continues in Germany.
- Enrollment was completed in the Phase 3 PRIMA trial for patients with first-line ovarian cancer regardless of biomarker status. Data from this study are anticipated in late 2019.
- Data were presented from the ovarian cancer cohort of the TOPACIO trial of ZEJULA in combination with an anti-PD-1 monoclonal antibody at the Society for Gynecologic Oncology (SGO) Annual Meeting in March. Data demonstrated activity of ZEJULA in combination with an anti-PD-1 antibody in difficult-to-treat types of ovarian cancer.
- Results from a retrospective analysis of the NOVA trial were presented at the SGO Annual Meeting, which identified two characteristics, patient body weight and platelet counts, to be predictors of dose modification.
- In April, preliminary Phase 1 data from expansion cohorts of the GARNET trial of TSR-042 were presented at the American Association for Cancer Research (AACR) Annual Meeting. Activity of TSR-042 monotherapy was demonstrated in patients with MSI-high endometrial cancer and non-small cell lung cancer (NSCLC), with a well-tolerated safety profile comparable to other anti-PD-1 antibodies.
- Top-line results from the QUADRA study of ZEJULA monotherapy in fourth-line plus treatment of ovarian cancer were announced in April. This trial successfully achieved its pre-specified primary endpoint and demonstrated activity in patients with fourth or fifth-line HRD-positive ovarian cancer who were PARP inhibitor naïve and platinum sensitive. Additional QUADRA data will be presented at ASCO in June.
- Phase 2 data from the TOPACIO trial of ZEJULA with an anti-PD-1 for patients with platinum-resistant ovarian cancer or triple-negative breast cancer were accepted for two separate oral presentations at ASCO.
- TSR-042 is in a registration trial (GARNET) for MSI-high tumors. Data are being generated to demonstrate the activity of TSR-042 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 is ongoing to determine dose and schedule for combination with TSR-042.

First Quarter 2018 Financial Results

TESARO reported net product revenue of $50.2 million for the first quarter of 2018, including ZEJULA sales of $48.9 million, compared to $2.1 million for the first quarter of 2017.

Research and development expenses increased to $96.8 million for the first quarter of 2018, compared to $66.1 million for the first quarter of 2017,

primarily due to higher manufacturing and clinical development costs associated with ZEJULA, TSR-042, and TSR-022, increased headcount, and research collaborations.

Selling, general and administrative expenses increased to $93.6 million for the first quarter of 2018, compared to $69.3 million for the first quarter of 2017, primarily due to increased sales and marketing headcount and activities to support sales of ZEJULA in the U.S. and launches in Europe.

Operating expenses as described above include total non-cash, stock-based compensation expense of $26.1 million for the first quarter of 2018, compared to $18.4 million for the first quarter of 2017.

Net loss totaled $162.8 million, or ($2.98) per share, for the first quarter of 2018, compared to a net loss of $136.7 million, or ($2.55) per share, for the first quarter of 2017.

(in thousands, except per share amounts)	**Three Months Ended March 31,**	
	2017	**2018**
Product revenue, net		
ZEJULA®	-	$ 48,869
VARUBI®/VARUBY®	$ 2,139	$ 1,303
Total product revenue, net	$ 2,139	$ 50,172
License, collaboration, and other revenue	$ 934	$ (430)
Total revenues	$ 3,073	$ 49,742
Net loss	$ (136,725)	$ (162,816)
Net loss per share, basic and diluted	$ (2.55)	$ (2.98)

Operating Expenses

(in thousands)	**Three Months Ended March 31,**	
	2017	**2018**
Cost of sales - product	$ 444	$ 9,997
Cost of sales - intangible asset amortization	$ 490	$ 1,437
Research and development (R&D)	$ 66,122	$ 96,755
Selling, general and administrative (SG&A)	$ 69,262	$ 93,607
Acquired in-process R&D	$ -	$ -

Cash and Cash Equivalents

As of March 31, 2018, TESARO had approximately $499.0 million in cash and cash equivalents and approximately 54.8 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 (Q2)	$50 to $55 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 the first quarter, TESARO's cash and cash equivalents balance declined by approximately $144 million. The Company plans to draw $200 million in the second half of 2018 from its available term loan facility, and quarterly declines in cash and cash equivalents are expected to moderate over the course of 2018. 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:

Ovarian Cancer Franchise:

- Report TOPACIO platinum-resistant ovarian cancer data at ASCO and confirm with FDA the intended strategy for registering ZEJULA in combination with TSR-042 in platinum-resistant/refractory ovarian cancer in mid-2018
- Initiate FIRST, a Phase 3 clinical trial of ZEJULA in combination with TSR-042 in first-line ovarian cancer, in Q2 2018

- Report QUADRA data at ASCO and define biomarker-focused regulatory strategy in 2H 2018
- Report PRIMA data in first-line ovarian cancer maintenance in late 2019

Breast Cancer:

- Report TOPACIO triple-negative breast cancer data at ASCO
- Publish BRAVO data in 2H 2018
- Confirm intended registration path for ZEJULA in breast cancer with FDA in mid-2018

Lung Cancer:

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

Prostate Cancer:

- Janssen anticipates advancing trials of ZEJULA 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 of TSR-042 to support a biologics license application (BLA) submission to FDA in 2019
- Report initial data for the AMBER trial of TSR-022 in combination with TSR-042 in 2H 2018
- 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 antibody (TSR-075)

Today's Conference Call and Webcast
TESARO will host a conference call to discuss first quarter 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 dedicated to improving the lives of cancer patients by acquiring, developing and commercializing safer and more effective therapeutics. 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, interest expense, and cash balance guidance; the expected decline in our cash and cash equivalents balance; 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 and other regulatory filings; and our expectation to achieve our various 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, 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.

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

	Three Months Ended March 31,	
	2017	**2018**
Revenues:		
Product revenue, net:		
ZEJULA®	$ -	$ 48,869
VARUBI®/VARUBY®	2,139	1,303
Total product revenue, net	2,139	50,172
License, collaboration and other revenues	934	(430)
Total revenues	3,073	49,742
Expenses:		
Cost of sales - product	444	9,997
Cost of sales - intangible asset amortization	490	1,437
Research and development (1)	66,122	96,755
Selling, general and administrative (1)	69,262	93,607
Acquired in-process research and development	-	-
Total expenses	136,318	201,796
Loss from operations	(133,245)	(152,054)
Interest and other income (expense), net	(3,426)	(10,346)
Loss before income taxes	(136,671)	(162,400)
Provision for income taxes	54	416
Net loss	$ (136,725)	$ (162,816)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.55)	$ (2.98)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	53,685	54,615

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

Research and development	$ 7,125	$ 7,814
Selling, general and administrative	11,276	18,314

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

	December 31, 2017	**March 31, 2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 643,095	$ 498,980
Accounts receivable	53,416	44,182
Inventories	57,939	74,444
Other current assets	33,511	38,184
Total current assets	787,961	655,790

Intangible assets, net	56,384	54,947
Property and equipment, net	9,652	10,272
Restricted cash	2,552	2,556
Other assets	5,636	6,127
Total assets	$ 862,185	$ 729,692
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,172	$ 5,079
Accrued expenses	154,808	150,589
Deferred revenue, current	324	117
Other current liabilities	6,902	7,451
Total current liabilities	166,206	163,236
Convertible notes, net	143,446	146,529
Long-term debt, net	293,659	293,888
Deferred revenue, non-current	211	188
Other non-current liabilities	9,577	8,123
Total liabilities	613,099	611,964
Total stockholders' equity	249,086	117,728
Total liabilities and stockholders' equity	$ 862,185	$ 729,692

Primary Logo

Source: TESARO, Inc.