TESARO Announces Second-Quarter 2018 Operating Results

August 2, 2018

- **ZEJULA® Q2 net sales totaled $54 million compared to $26 million for Q2 2017**
- **QUADRA sNDA submission planned for Q4 2018**
- **PRIMA Phase 3 ZEJULA monotherapy trial in first-line ovarian cancer regardless of biomarker status enrollment completed**
- **Divestiture completed for VARUBI in U.S. and Canada for $40 million plus potential milestone payments and royalties**
- **Data expected from TSR-042 (anti-PD-1) GARNET NSCLC and MSI-high endometrial expansion cohorts in 2H 2018; regulatory submission planned for 2019**

WALTHAM, Mass., Aug. 02, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ: TSRO), an oncology-focused biopharmaceutical company, today reported operating results for second-quarter 2018 and provided an update on the Company's commercial products and development programs.

“In the second quarter, we continued to execute on the ZEJULA launch in the U.S. and Europe, and we are changing the treatment paradigm for women with recurrent ovarian cancer,” said Lonnie Moulder, CEO of TESARO. “Following the results from our Phase 3 PRIMA trial, which is now fully enrolled, we hope to offer ZEJULA to women with newly diagnosed ovarian cancer, regardless of *BRCA* mutation status. Beyond ovarian cancer, our Phase 2 JASPER trial of ZEJULA in combination with an anti-PD-1 antibody in first-line, non-small cell lung cancer is ongoing and we expect to share data at a medical meeting in the first half of 2019. Our immuno-oncology pipeline is advancing quickly, led by TSR-042, our anti-PD-1 antibody, for which we are on track to submit a biologic license application (BLA) in 2019. Initial data from AMBER, a trial of our anti-TIM-3 antibody TSR-022 in combination with TSR-042, have been submitted for inclusion in the SITC Annual Meeting in November, and include results from lung cancer patients who have progressed on prior anti-PD-1 treatment.”

Recent Business Highlights

- ZEJULA is the most utilized PARP inhibitor among ovarian cancer patients in the U.S., with more than 6,000 patients treated since its launch in April 2017. ZEJULA is now approved in 32 countries and reimbursed and launched in Germany, the U.K. and several other European countries.
- The National Institute for Health and Care Excellence (NICE) made ZEJULA available to women with recurrent platinum-sensitive ovarian cancer in England and Wales via the Cancer Drugs Fund (CDF) in June.
- At the ASCO meeting in June, results of the QUADRA study of ZEJULA monotherapy for the treatment of ovarian cancer were presented and included durable responses beyond patients with *BRCA* mutations and overall survival in the late-line ovarian cancer treatment setting. Results of the TOPACIO trial evaluating ZEJULA in combination with an anti-PD-1 antibody were also presented and highlighted promising activity in platinum-resistant/refractory ovarian cancer and triple-negative breast cancer beyond patients with *BRCA* mutations.
- Enrollment was completed in the Phase 3 PRIMA trial of ZEJULA monotherapy for patients with first-line ovarian cancer regardless of biomarker status, and data from this study are anticipated in late 2019. Blinded, pooled interim safety data from PRIMA associated with a 200 milligram starting dose based upon baseline weight and platelet count were accepted for poster discussion at the European Society of Medical Oncology (ESMO) Annual Meeting in October.
- TESARO divested the oral and intravenous formulations of VARUBI® (rolapitant) in the U.S. and Canada to TerSera Therapeutics LLC for $40 million plus potential milestone payments and royalties.
- Data from the GARNET registration trial for TSR-042 (anti-PD-1 antibody) in patients with MSI-high endometrial cancer were accepted for poster discussion at the ESMO Annual Meeting in October.
- Enrollment continues in the Phase 1 AMBER trial of TSR-022 (anti-TIM-3 antibody) in combination with TSR-042 in tumor-specific cohorts, including lung cancer patients who have progressed on prior PD-1 therapy.
- In the Phase 1 CITRINO trial, dosing of TSR-033 (anti-LAG-3 antibody) in combination with TSR-042 was initiated.
- At the end of June, TESARO drew the $200 million second tranche under its term loan agreement with Pharmakon Advisors, LP.

Second Quarter 2018 Financial Results

TESARO reported net product revenue of $56.5 million for the second quarter of 2018, compared to a total of $28.8 million for the second quarter of 2017, primarily due to growth in ZEJULA net revenue, which increased 108% to $53.9 million for the second quarter of 2018, compared to $25.9 million for the second quarter of 2017.

Research and development expenses increased to $97.6 million for the second quarter of 2018, compared to $71.4 million for the second quarter of

2017, primarily due to higher costs associated with the development of ZEJULA, TSR-042 and TSR-022, increased headcount, and research collaborations.

Selling, general and administrative expenses increased to $100.0 million for the second quarter of 2018, compared to $93.0 million for the second quarter of 2017, primarily due to increased headcount 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 $28.4 million for the second quarter of 2018, compared to $23.5 million for the second quarter of 2017.

Net loss totaled $166.7 million, or ($3.04) per share, for the second quarter of 2018, compared to a net loss of $152.1 million, or ($2.82) per share, for the second quarter of 2017.

(in thousands, except per share amounts)	**Three Months Ended June 30,**	
	2017	**2018**
Product revenue, net		
ZEJULA®	$ 25,945	$ 53,894
VARUBI®/VARUBY®	$ 2,884	$ 2,634
Total product revenue, net	$ 28,829	$ 56,528
License, collaboration, and other revenue	$ 635	$ 680
Total revenues	$ 29,464	$ 57,208
Net loss	$ (152,059)	$ (166,651)
Net loss per share, basic and diluted	$ (2.82)	$ (3.04)

(in thousands)	**Three Months Ended June 30,**	
	2017	**2018**
Cost of sales - product	$ 3,620	$ 13,513
Cost of sales - intangible asset amortization	$ 2,979	$ 1,498
Research and development (R&D)	$ 71,400	$ 97,608
Selling, general and administrative (SG&A)	$ 92,979	$ 100,033
Acquired in-process R&D	$ 7,000	$ -

Cash and Cash Equivalents

As of June 30, 2018, TESARO had approximately $575.1 million in cash and cash equivalents, excluding $35 million received from TerSera in the third quarter upon closing of the VARUBI divestiture, and approximately 54.9 million outstanding shares of common stock.

2018 Financial Guidance

TESARO is revising its 2018 financial guidance to reflect the divestiture of VARUBI in the U.S. and Canada, updated timing of clinical milestone payments, and updated expectations for the market penetration of PARP inhibitors for ovarian cancer maintenance treatment in the U.S.

Total Revenue, net, worldwide (FY)	$250 to $265 million (previously $310 to $345 million)
ZEJULA (FY)	$225 to $235 million (previously $255 to $275 million)
ZEJULA (Q3)	$58 to $62 million
Other revenue, including licensing and VARUBY oral (FY)	$25 to $30 million (previously $55 to $70 million)
Interest expense (FY)	$50 to $60 million, including non-cash interest expense of $14 million

In the second quarter, TESARO's cash and cash equivalents balance declined by approximately $120 million, excluding the impact of the $196 million (net of lender fees) received from the term loan facility. Quarterly declines in cash and cash equivalents are expected to moderate over the remainder of 2018 and TESARO anticipates year-end 2018 cash and cash equivalents to be approximately $400 million, including the $35 million upfront payment received in the third quarter from the divestiture of VARUBI.

Key Development Milestones

Gynecologic Cancer:

- Submit QUADRA sNDA for treatment of late-line ovarian cancer beyond *BRCA*mut patients in Q4 2018
- Initiate registrational trial of ZEJULA in combination with TSR-042 in platinum-resistant/refractory ovarian cancer in Q4 2018
- Initiate enrollment in FIRST, a Phase 3 clinical trial of ZEJULA in combination with TSR-042 ± bevacizumab in first-line ovarian cancer, in September 2018
- AVANOVA Phase 2 data 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 data of ZEJULA in combination with bevacizumab in first-line ovarian cancer maintenance in late 2019
- Report Phase 3 PRIMA data of ZEJULA in first-line ovarian cancer maintenance in late 2019
- Report additional data from MSI-high endometrial cohort of the GARNET trial of TSR-042 at the ESMO Annual Meeting in October and submit a BLA to FDA in 2H 2019

Lung Cancer:

- Initiate Phase 2 registration enabling trial of TSR-042 versus standard of care in first-line NSCLC in early 2019
- Report additional data from lung cancer cohort of the GARNET trial of TSR-042 in NSCLC at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November
- Report initial data from the AMBER trial of TSR-022 in combination with TSR-042 at the SITC Annual Meeting
- Following availability of initial data in Q4 2018 from Phase 2 JASPER study of ZEJULA in combination with an anti-PD-1 inhibitor, submit data for presentation at a medical meeting in 1H 2019

Breast Cancer:

- Submit BRAVO data for publication in Q4 2018
- Complete protocol development for registration study of ZEJULA in combination with TSR-042 in breast cancer

Prostate Cancer:

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

Immuno-oncology Pipeline:

- Continue to enroll CITRINO trial (combination of TSR-033 plus TSR-042) and report Phase 1 monotherapy dose-escalation data for TSR-033 at the SITC Annual Meeting
- 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 second 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, 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 March 31, 2018.

TESARO, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2018	2017	2018
Revenues:				
Product revenue, net:				
ZEJULA®	$ 25,945	$ 53,894	$ 25,945	$ 102,763
VARUBI®/VARUBY®	2,884	2,634	5,023	3,937
Total product revenue, net	28,829	56,528	30,968	106,700
License, collaboration and other revenues	635	680	1,569	250
Total revenues	29,464	57,208	32,537	106,950
Expenses:				
Cost of sales - product	3,620	13,513	4,064	23,510
Cost of sales - intangible asset amortization	2,979	1,498	3,469	2,935
Research and development (1)	71,400	97,608	137,522	194,363
Selling, general and administrative (1)	92,979	100,033	162,241	193,640
Acquired in-process research and development	7,000	-	7,000	-
Total expenses	177,978	212,652	314,296	414,448
Loss from operations	(148,514)	(155,444)	(281,759)	(307,498)
Interest and other income (expense), net	(3,467)	(11,215)	(6,893)	(21,561)
Loss before income taxes	(151,981)	(166,659)	(288,652)	(329,059)
Provision (benefit) for income taxes	78	(8)	132	408
Net loss	$ (152,059)	$ (166,651)	$ (288,784)	$ (329,467)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.82)	$ (3.04)	$ (5.36)	$ (6.02)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	53,982	54,845	53,834	54,731

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

Research and development	$ 7,862	$ 8,195	$ 14,987	$ 16,009
Selling, general and administrative	15,646	20,214	26,922	38,528

TESARO, Inc.

Unaudited Condensed Consolidated Balance Sheets

(in thousands)

	December 31, 2017	June 30, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 643,095	$ 575,104
Accounts receivable	53,416	35,679
Inventories	57,939	87,406
Other current assets	33,511	36,924
Assets held for sale	-	22,299
Total current assets	787,961	757,412
Intangible assets, net	56,384	36,624
Property and equipment, net	9,652	10,657
Restricted cash	2,552	2,556
Other assets	5,636	3,204
Total assets	$ 862,185	$ 810,453
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,172	$ 12,925
Accrued expenses	154,808	159,447
Deferred revenue, current	324	437
Other current liabilities	6,902	11,371
Total current liabilities	166,206	184,180
Convertible notes, net	143,446	149,793
Long-term debt, net	293,659	490,125
Deferred revenue, non-current	211	164
Other non-current liabilities	9,577	7,739
Total liabilities	613,099	832,001
Total stockholders' equity (deficit)	249,086	(21,548)
Total liabilities and stockholders' equity (deficit)	$ 862,185	$ 810,453


Primary Logo

Source: TESARO, Inc.