Endocyte, Inc. Logo

Endocyte Provides Second Quarter 2018 Financial Results and Operational Update

July 31, 2018

-Initiated phase 3 VISION study of ^{177}Lu-PSMA-617 in mCRPC-

-Secured commercial supply of no-carrier-added Lutetium-177 through 2035-

-Investigational new drug (IND) filing for EC17/CAR T-cell therapy on track for fourth quarter 2018-

-Conference call today at 8:30 a.m. EDT-

WEST LAFAYETTE, Ind., July 31, 2018 (GLOBE NEWSWIRE) -- Endocyte, Inc. (Nasdaq:ECYT), a biopharmaceutical company developing targeted therapeutics for personalized cancer treatment, today announced financial results for the second quarter ending June 30, 2018 and provided an operational update.

"During the second quarter, we continued to execute rapidly on our strategy, initiating the phase 3 VISION study of ^{177}Lu-PSMA-617 and securing a long-term commercial supply agreement for no-carrier added lutetium, which could support treatment of a potentially large patient population if approved," said Mike Sherman president and CEO of Endocyte. "Additionally, data from ^{177}Lu-PSMA-617 were prominently featured at key medical meetings during the quarter, and we are pleased that data continue to suggest a favorable profile and improved PSA response rates. We also presented key preclinical data from our CAR-T platform and expect to file an IND for EC17/CAR T-cell therapy in patients with osteosarcoma in the fourth quarter this year."

Second Quarter and Recent Highlights

- Enrolled the first patient in the phase 3 VISION study of ^{177}Lu-PSMA-617 in patients with progressive prostate specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC).
- Signed a long-term global supply agreement with ITG Isotope Technologies Garching GmbH (ITG), for highly purified, no-carrier-added Lutetium-177 to support both clinical and commercial supply of ^{177}Lu-PSMA-617, through 2035.
- Announced that multiple presentations related to Endocyte's PSMA-617 radioligand therapy were presented at the 2018 Society of Nuclear Medicine and Molecular Imaging Annual Meeting.
- Announced the publication of data in *The Lancet Oncology* from the original 30 patients in the phase 2 trial of ^{177}Lu-PSMA-617 initiated by Professor Michael Hofman of the Peter MacCallum Cancer Centre (MacCallum study). Relative to previously presented data from this study, the updated data reflected longer median overall survival, longer median prostate specific antigen (PSA) progression-free survival, and higher RECIST soft tissue response rates. The safety profile of ^{177}Lu-PSMA-617 was similar to that previously reported.
- Announced the presentation of data at the American Society of Clinical Oncology Annual Meeting from 50 patients in the MacCallum study, which included data from 20 additional patients and demonstrated higher PSA response rates than the initial 30 patients in the study, as well as consistency in activity regardless of prior therapies. Survival data from these additional 20 patients were not yet mature.
- Presented data at the American Association for Cancer Research Annual Meeting, including a late-breaking poster, demonstrating that EC17/CAR T-cell therapy showed consistent antitumor activity in human xenografts, with multiple mechanisms for controlling immune response to potentially mitigate cytokine release syndrome.

Expected 2018 Milestones

- Publications on additional ongoing investigator-initiated clinical trials of ^{177}Lu-PSMA-617 in prostate cancer patients (2018).
- IND for phase 1 trial of EC17/CAR T-cell therapy in patients with osteosarcoma (4Q 2018).

Second Quarter 2018 Financial Results

Endocyte reported a net loss of $11.6 million, or $0.17 per basic and diluted share, for the second quarter of 2018, compared to a net loss of $11.7 million, or $0.28 per basic and diluted share, for the same period in 2017.

Research and development expenses were $7.6 million for the second quarter of 2018, compared to $8.7 million for the same period in 2017. The decrease was primarily attributable to a strategic portfolio review announced in June 2017 which led to a reduction in workforce and the discontinuation of certain research and development activities, including, for the second quarter of 2018 compared to the second quarter of 2017: a decrease of $1.5 million in EC1456 trial expenses; a decrease of $1.3 million in expenses related to pre-clinical work and general research, including the development of EC2629; a decrease of $1.0 million in EC1169 trial expenses; a decrease of $0.5 million in compensation expense as a result of employee terminations since June 30, 2017; and a decrease of $0.2 million in manufacturing expense for EC1169 and EC1456. These decreases were partially offset by: an increase of $3.3 million in expenses related to development of PSMA-617; and an increase of $0.2 million related to our CAR T-cell therapy program.

General and administrative expenses were $4.6 million for the second quarter of 2018, compared to $3.3 million for the same period in 2017. The increase was primarily attributable to an increase of $0.5 million in compensation expense, of which $0.4 million related to stock-based compensation

charges; an increase of $0.5 million in legal and professional fees; and an increase of $0.3 million in other general and administrative fees.

Cash, cash equivalents and investments were $166.8 million at June 30, 2018, compared to $118.4 million at June 30, 2017, and $97.5 million at Dec. 31, 2017. Cash, cash equivalents and investments of $166.8 million at June 30, 2018 included $80.9 million of net proceeds from our public offering of 20,535,714 shares of our common stock that closed in March 2018.

Financial Expectations

The company anticipates its cash, cash equivalents and investments balance at the end of 2018 to exceed $130 million. Based on current operational assumptions, Endocyte has sufficient cash to fund its activities through the expected end of the VISION trial and potential proof of concept of its EC17/CAR T-cell therapy.

Conference Call

Endocyte management will host a conference call today at 8:30 a.m. EDT.

U.S. and Canadian participants: (877) 845-0711
International: (760) 298-5081

A live, listen-only webcast of the conference call may be accessed by visiting the Investors & News section of the Endocyte website, www.endocyte.com.

The webcast will be recorded and available on the company's website for 90 days following the call.

Website Information
Endocyte routinely posts important information for investors on its website, www.endocyte.com, in the “Investors & News” section. Endocyte uses this website as a means of disclosing material information in compliance with its disclosure obligations under Regulation FD. Accordingly, investors should monitor the “Investors & News” section of Endocyte’s website, in addition to following its press releases, SEC filings, public conference calls, presentations and webcasts. The information contained on, or that may be accessed through, Endocyte’s website is not incorporated by reference into, and is not a part of, this document.

About Endocyte

Endocyte is a biopharmaceutical company and leader in developing targeted therapies for the personalized treatment of cancer. The company's drug conjugation technology targets therapeutics and companion imaging agents specifically to the site of diseased cells. Endocyte's lead program is a prostate specific membrane antigen (PSMA)-targeted radioligand therapy, ^{177}Lu-PSMA-617, in phase 3 for metastatic castration-resistant prostate cancer (mCRPC). Endocyte also expects to have an Investigational New Drug application submitted in the fourth quarter of 2018 for its adaptor-controlled CAR T-cell therapy which will be studied initially in osteosarcoma. For additional information, please visit Endocyte's website at www.endocyte.com.

Forward Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, relating to future spending, future cash balances, future use of capital, sufficiency of cash, the timing of initiation, interim assessments and completion of clinical trials, the enrollment period for, and availability and reporting of data from, ongoing and future clinical trials, the occurrence and timing of submissions to, and actions by, regulatory agencies, estimates of the potential market opportunity for the company’s product candidates, and the company's future development plans including those relating to the completion of pre-clinical development in preparation for possible future clinical trials and future sources of supply of raw materials and product candidates to support clinical and commercial activities. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include risks that the company or independent investigators may experience delays in the initiation or completion of clinical trials (whether caused by competition, adverse events, patient enrollment rates, shortage of clinical trial materials, regulatory issues or other factors); risks that suppliers or other third party contractors may not fulfill their contractual obligations on a timely basis or at all; risks that data from prior clinical trials may not be indicative of subsequent clinical trial results; risks related to the safety and efficacy of the company’s product candidates; risks that early stage pre-clinical data may not be indicative of subsequent data when expanded to additional pre-clinical models or to subsequent clinical data; risks that evolving competitive activity and intellectual property landscape may impair the company'sability to capture value for thetechnology; risks that expectations and estimates turn out to be incorrect, including estimates of the potential markets for the company’s product candidates, estimates of the capacity of manufacturing and other facilities required to support its product candidates, projected cash needs, and expected future revenues, operations, expenditures and cash position. More information about the risks and uncertainties faced by Endocyte, Inc. is contained in the company’s periodic reports filed with the Securities and Exchange Commission. Endocyte, Inc. disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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Endocyte, Inc.
Statements of Operations
(dollars in thousands, except per share amounts)
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	**2018**	**2017**	**2018**

Collaboration revenue	$ 13	$ 14	$ 25	$ 30
Costs and expenses:				
Research and development	8,655	7,625	16,649	12,880
General and administrative	3,306	4,631	7,051	8,409
Total costs and expenses	11,961	12,256	23,700	21,289
Loss from operations	(11,948)	(12,242)	(23,675)	(21,259)
Interest income, net	234	720	469	1,133
Other expense, net	(30)	(42)	(27)	(41)
Net loss	$ (11,744)	$ (11,564)	$ (23,233)	$ (20,167)
Net loss per share - basic and diluted	$ (0.28)	$ (0.17)	$ (0.55)	$ (0.32)
Comprehensive loss	$ (11,726)	$ (11,520)	$ (23,227)	$ (20,137)
Weighted average number of common shares used in net loss per share calculation – basic and diluted	42,503,584	69,712,883	42,469,337	62,397,454

Endocyte, Inc.
Balance Sheets
(in thousands)

	As of December 31, 2017	**As of June 30, 2018** (unaudited)
Assets		
Cash, cash equivalents and investments	$ 97,471	$ 166,793
Other assets	3,291	5,376
Total assets	$ 100,762	$ 172,169
Liabilities and stockholders' equity		
Current liabilities	$ 4,546	$ 5,954
Deferred revenue, net of current portion	732	349
Total stockholders' equity	95,484	165,866
Total liabilities and stockholders' equity	$ 100,762	$ 172,169

Primary Logo

Source: Endocyte, Inc.