Endocyte, Inc. Logo

Endocyte Provides Third Quarter 2018 Financial Results and Operational Update

November 7, 2018

Entered into agreement and plan of merger with Novartis AG for $2.1Billion

WEST LAFAYETTE, Ind., Nov. 07, 2018 (GLOBE NEWSWIRE) -- Endocyte, Inc. (Nasdaq:ECYT), a biopharmaceutical company developing targeted therapeutics for personalized cancer treatment, today announced financial results for the third quarter ended Sept. 30, 2018 and provided an operational update.

"^{177}Lu-PSMA-617's value as a potential treatment for patients with mCRPC has been reinforced in both our regulatory interactions and our entry into a merger agreement with Novartis AG, along with our longstanding interactions with patients and physicians in the prostate cancer community," said Mike Sherman, president and CEO of Endocyte. "The team at Endocyte has always been passionate about developing innovative therapies to help change the treatment landscape for cancer patients, and we look forward to being able to leverage Novartis' global expertise and commitment to help realize this mission."

Third Quarter and Recent Highlights

- Announced on October 18, 2018, our entry into an agreement and plan of merger with Novartis AG (Novartis), subject to the terms and conditions of which Novartis will acquire Endocyte for $24 per share, or a total equity value of approximately $2.1 billion, in cash. The merger price represents a premium of 54% to Endocyte's closing price of $15.56 on October 17, 2018.
- Announced FDA acceptance of radiographic progression free survival (rPFS) as an alternative primary endpoint of the ongoing phase 3 VISION trial to support the submission of a New Drug Application (NDA) for full approval of ^{177}Lu-PSMA-617 for the treatment of metastatic castration-resistant prostate cancer (mCRPC).
- Completed an underwritten registered public offering of 10,878,379 shares of its common stock, including full exercise of the underwriters' option to purchase additional shares of common stock, raising aggregate net proceeds from the offering of $188.9 million.
- Presented pre-clinical data from the company's chimeric antigen receptor T-cell (CAR T) adaptor molecule (CAM) platform at CAR-TCR Summit 2018.

Expected Upcoming Milestones

- Submission of an Investigational New Drug (IND) application for a phase 1 trial of EC17/CAR T-cell therapy in patients with osteosarcoma (4Q 2018).
- Completion of the proposed transaction between Endocyte and Novartis expected in 1H 2019, subject to approval by Endocyte stockholders, antitrust and regulatory approvals, and other customary closing conditions.
- Analysis of rPFS in VISION trial (late 2019).

Third Quarter 2018 Financial Results

Endocyte reported a net loss of $12.6 million, or $0.17 per basic and diluted share, for the third quarter of 2018, compared to a net loss of $23.3 million, or $0.55 per basic and diluted share, for the same period in 2017.

Research and development expenses were $8.9 million for the third quarter of 2018, compared to $4.1 million for the same period in 2017. The increase was primarily attributable to: an increase of $4.5 million in expenses related to development of PSMA-617, including expenses related to the phase 3 VISION trial; an increase of $1.2 million in compensation expense, of which $0.4 million related to stock-based compensation charges; and an increase of $0.1 million related to the company's EC17/CAR T-cell therapy program. These increases were partially offset by a decrease of $0.8 million in EC1169 trial expenses and a decrease of $0.2 million for general research.

General and administrative expenses were $4.8 million for the third quarter of 2018, compared to $3.0 million for the same period in 2017. The increase was primarily attributable to: an increase of $0.8 million in compensation expense, of which $0.5 million related to stock-based compensation charges; an increase of $0.6 million in legal and professional fees; and an increase of $0.4 million in other general and administrative fees.

In September 2017, the company recorded $16.5 million of acquired in-process research and development ("IPR&D") expenses related to a development and license agreement with ABX GmbH that granted the company exclusive worldwide rights to develop and commercialize PSMA-617, including the product candidate known as ^{177}Lu-PSMA-617. The company did not incur any IPR&D expenses in the third quarter of 2018.

Cash, cash equivalents and investments were $344.2 million at September 30, 2018, compared to $103.1 million at September 30, 2017, and $97.5 million at Dec. 31, 2017. Cash, cash equivalents and investments of $344.2 million at September 30, 2018 included $188.9 million of net proceeds from the public offering of 10,878,379 shares of the company's common stock that closed in September 2018.

Financial Expectations

The company anticipates its cash, cash equivalents and investments balance at the end of 2018 to exceed $310 million. Based on current operational assumptions, Endocyte believes it 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.

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.

Additional Information and Where to Find It

In connection with the proposed transaction between Endocyte, Inc. (“Endocyte”) and Novartis AG (the “merger”), Endocyte has filed and intends to file relevant materials with the Securities and Exchange Commission (the “SEC”). Endocyte filed a preliminary proxy statement with the SEC on October 31, 2018, and intends to file a definitive proxy statement with the SEC. Following the filing of the definitive proxy statement with the SEC, Endocyte will mail definitive proxy materials to each stockholder entitled to vote at the special meeting relating to the merger. **Stockholders are urged to carefully read the proxy statement and any other proxy materials in their entirety (including any amendments or supplements thereto) and any other relevant documents that Endocyte will file with the SEC when they become available because they will contain important information.** The proxy statement and other relevant materials (when available), and any and all documents filed by Endocyte with the SEC, may also be obtained for free at the SEC’s website at www.sec.gov. In addition, stockholders may obtain free copies of the documents filed with the SEC by Endocyte in the “Investors & News” section of its website at www.endocyte.com, or copies may be obtained, without charge, by directing a request to Corporate Secretary, Endocyte, Inc., 8910 Purdue Road, Suite 250, Indianapolis, Indiana 46268 or by calling (765) 463-7175.

Participants in the Solicitation

Endocyte and its directors and executive officers may be deemed, under SEC rules, to be participants in the solicitation of proxies from Endocyte’s stockholders with respect to the merger. Information regarding such individuals is set forth in Endocyte’s Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the SEC on February 27, 2018, and its definitive proxy statement for its 2018 annual meeting of stockholders, which was filed with the SEC on March 23, 2018. Additional information regarding the interests of such individuals in the merger is included in Endocyte’s preliminary proxy statement filed with the SEC and will be included in the definitive proxy statement relating to the merger when it is filed with the SEC. These documents may be obtained free of charge from the SEC’s website at www.sec.gov and 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 the merger, future spending, future cash balances, future use of capital, sufficiency of cash, the timing of initiation, enrollment, and completion of clinical trials, the likelihood of success of clinical trials and of regulatory approval for product candidates, the timing of regulatory submissions for product candidates, estimates of the market opportunity for 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 in support of 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 may be unable to obtain stockholder approval as required for the merger; conditions to the closing of the merger, including the obtaining of required regulatory approvals, may not be satisfied; the merger may involve unexpected costs, liabilities or delays; the business or stock price of the company may suffer as a result of uncertainty surrounding the merger; the outcome of legal proceedings related to the merger; the company may be adversely affected by other economic, business, and/or competitive factors; the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement; the ability to recognize benefits of the merger; risks that the merger disrupts current plans and operations and the potential difficulties in employee retention as a result of the merger; other risks to consummation of the merger, including the risk that the merger will not be consummated within the expected time period or at all; the company or independent investigators may experience delays in the initiation, availability of data from, or completion of clinical trials and development programs (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 lack of safety and/or 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’s ability to capture value for the technology; risks related to the company’s inability to maintain, protect and enhance its intellectual property; risks related to costs associated with defending intellectual property infringement and other claims; 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, supply chain issues of any type, including timing of supply, projected cash needs, projected timing of the use of cash, and expected future revenues, operations, expenditures and cash position. More information about the risks and uncertainties faced by Endocyte is contained in the company’s periodic reports filed with the SEC. Endocyte 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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Statements of Operations
(dollars in thousands, except per share amounts)
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2018	2017	2018
Collaboration revenue	$ 33	$ 86	$ 58	$ 116
Costs and expenses:				
Research and development	4,090	8,856	20,739	21,736
General and administrative	3,011	4,789	10,062	13,198
Acquired in-process research and development	16,493	-	16,493	-
Total operating expenses	23,594	13,645	47,294	34,934
Loss from operations	(23,561)	(13,559)	(47,236)	(34,818)
Interest income, net	265	959	734	2,092
Other income (expense), net	29	(8)	2	(49)
Net loss	$ (23,267)	$ (12,608)	$ (46,500)	$ (32,775)
Net loss per share - basic and diluted	$ (0.55)	$ (0.17)	$ (1.09)	$ (0.50)
Comprehensive loss	$ (23,237)	$ (12,596)	$ (46,463)	$ (32,733)
Weighted average number of common shares used in net loss per share calculation – basic and diluted	42,636,567	72,043,113	42,525,693	65,648,006

Endocyte, Inc.
Balance Sheets
(in thousands)

	As of December 31, 2017	As of September 30, 2018
		(unaudited)
Assets		
Cash, cash equivalents and investments	$ 97,471	$ 344,210
Other assets	3,291	10,994
Total assets	$ 100,762	$ 355,204
Liabilities and stockholders' equity		
Current liabilities	$ 4,546	$ 7,675
Deferred revenue, net of current portion	732	332
Total stockholders' equity	95,484	347,197
Total liabilities and stockholders' equity	$ 100,762	$ 355,204