

# ENDOCYTE INC

## **FORM 8-K** (Current report filing)

Filed 08/08/17 for the Period Ending 08/08/17

Address	3000 KENT AVE STE A1-100 WEST LAFAYETTE, IN 47906
Telephone	7654637175
CIK	0001235007
Symbol	ECYT
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

---

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): August 8, 2017

Endocyte, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-35050 (Commission File Number)	35-1969-140 (I.R.S. Employer Identification No.)
3000 Kent Avenue, Suite A1-100, West Lafayette, Indiana (Address of principal executive offices)		47906 (Zip Code)
Registrant's telephone number, including area code:		765-463-7175
Not Applicable Former name or former address, if changed since last report		

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

---

---

**ITEM 2.02 Results of Operations and Financial Condition.**

On August 8, 2017, Endocyte, Inc. (the “Company”) announced its results of operations for the three months ended June 30, 2017. A copy of the Company’s earnings release is furnished herewith as Exhibit 99.1.

**ITEM 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release issued on August 8, 2017

The information in this Current Report (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report (including Exhibit 99.1) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

---

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Endocyte, Inc.

August 8, 2017

By: /s/ Beth A. Taylor

Name: Beth A. Taylor

Title: *Vice President of Finance and Chief Accounting Officer*

---

Exhibit Index

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press release issued on August 8, 2017

---

Contact:  
Stephanie Ascher, Stern Investor Relations, Inc., (212) 362-1200, stephanie@sternir.com

## NEWS RELEASE

# Endocyte Reports Second Quarter Financial Results and Provides Clinical and Pipeline Update

*- Plans to Initiate Clinical Development for CAR T-Cell Program in Osteosarcoma in 2018 -*

*- Nearing Completion of Enrollment of Expansion Phase of EC1169 Trial in Prostate Cancer Patients -*

*- IND filed for Dual-Targeted DNA Crosslinker EC2629 -*

*- Conference Call Today at 4:30 p.m. EDT -*

**West Lafayette, Ind., Aug. 8, 2017** – Endocyte, Inc. (NASDAQ Global Market: ECYT), a leader in developing targeted small molecule drug conjugates (SMDCs) and companion imaging agents for personalized therapy, today announced financial results for the second quarter ending June 30, 2017, and provided a clinical and pipeline update.

“We’ve continued to make important progress on each of our three development programs,” said Mike Sherman, President and CEO of Endocyte. “Dr. Michael Jensen at the Seattle Children’s Research Institute has exceeded our expectations in the breadth of work he has completed in optimizing the vector to be used in our chimeric antigen receptor T-cell (CAR T-cell) therapy, and we are happy to report that we expect to initiate the CAR T-cell manufacturing process for clinical supply in the fourth quarter of this year. In addition, we have filed an Investigational New Drug (IND) application for EC2629, which we believe is the first agent in development that simultaneously targets cancer cells and the tumor associated macrophages (TAMs) that support and protect them – an approach that could continue to evolve the immunotherapy treatment landscape. Finally, we expect to complete enrollment of taxane-exposed prostate cancer patients in the EC1169, PSMA-tubulysin expansion trial this fall.”

“We believe our pipeline has significant potential to create value and we are committed to effective, timely execution in bringing these assets forward through clinical development and identifying paths to accelerate value-driving catalysts. With this in mind, our strategy is to select receptor-positive patients in highly-targeted indications from the beginning of development, including during dose escalation,” continued Mr. Sherman. “We will also continue to objectively measure our pipeline investments relative to opportunities to outlicense assets or access external opportunities to ensure we are deploying capital productively.”

### Development Programs Overview

**CAR T-Cell (Bi-specific adaptor molecule):** Today, Endocyte announced that Dr. Michael Jensen of Seattle Children’s Research Institute will lead the clinical evaluation of Endocyte’s first CAR T-cell adaptor molecule in patients with osteosarcoma. This is primarily a pediatric indication with a significant need for new therapeutic options. Recent results from tumor micro-array analysis and human intravital fluorescent imaging studies have confirmed this disease as positive for the folate receptor, the target of Endocyte’s first bi-specific adaptor. Pre-clinical evaluations for the CAR T-cell program by Dr. Jensen are expected to be completed in the second half of 2017, in anticipation of a potential IND filing in 2018. Multiple additional adaptor molecules designed to be directed to distinct tumor targets including, potentially, PSMA, NK1R and others, are in development through the company’s collaboration with Purdue University.

In April, Endocyte announced new research in a late-breaking poster session at the American Association for Cancer Research (AACR) Annual Meeting on this application of Endocyte’s SMDC technology. Data demonstrated that Endocyte’s bi-specific adaptor molecules can mitigate or eliminate adverse cytokine storms in animal models which could meaningfully improve the safety and tolerability of CAR T-cell therapies.

**EC1169 (PSMA-targeted tubulysin):** Endocyte is currently enrolling a phase 1 expansion cohort of 40 metastatic castration-resistant prostate cancer (mCRPC) patients who have previously been treated with a taxane-based therapy. Data presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in June demonstrated EC1169’s anti-tumor activity particularly in patients with previous exposure to taxane therapy. Endocyte stopped enrollment of taxane-naïve mCRPC patients in the trial in June. Updated interim results will be presented at the annual meeting of the European Society for Medical Oncology (ESMO) in September. This presentation is expected to be an incremental update to data presented at ASCO a few months prior. Completion of enrollment is expected in the fall.

**EC2629 (Folate-targeted PBD):** Endocyte recently filed an IND with the U.S. FDA and is planning to initiate a phase 1 clinical trial in patients selected as positive for the folate receptor in cancers where TAMs are known to be prevalent in the tumor micro-environment, for

---

example, breast, endometrial, ovarian, and non-small cell lung cancers. This novel agent leverages a proprietary DNA crosslinking warhead targeted to cancer cells and the TAMs that both support their growth as well as protect them from the immune system. This mechanism is particularly compelling in light of recent research that has identified mechanisms by which TAMs can mediate resistance to the use of checkpoint inhibitor therapies such as PD-1 and PD-L1.

### **Financial Expectations**

The company anticipates its cash, cash equivalents and investments balance at the end of 2017 to be approximately \$105 million. As the full expense impact of the company's restructuring is expected to be realized by the end of the fourth quarter of 2017, the company anticipates cash expenses to be approximately \$5 million per quarter prior to potential increases associated with advancing clinical trials and new investment opportunities currently under evaluation.

### **Second Quarter 2017 Financial Results**

Endocyte reported a net loss of \$11.7 million, or \$0.28 per basic and diluted share, for the second quarter of 2017, compared to a net loss of \$14.0 million, or \$0.33 per basic and diluted share for the same period in 2016.

In June 2017, the company stopped enrollment in its EC1456 phase 1b trial as the assessment of trial data did not yield the level of clinical activity necessary to support continued advancement of EC1456. The company is, however, continuing enrollment of a small number of patients in its EC1456 ovarian cancer surgical study to inform other SMDC programs in development. In addition, in June, Endocyte narrowed the focus of its EC1169 development program, refocused its efforts on two pre-clinical programs, and reduced its workforce by approximately 40% to align resources to focus aggressively on the company's highest value opportunities while maintaining key capabilities. Endocyte recorded \$2.3 million of restructuring expenses for the three months ended June 30, 2017 as follows:

- Included in research and development expenses were expenses for employee termination benefits of \$0.9 million, \$0.9 million for the remaining EC1456 phase 1b trial expenses, including site close-out expenses, \$0.3 million related to other restructuring expenses, and \$0.1 million related to fixed asset impairment charges; and
- Included in general and administrative expenses were expenses for employee termination benefits of \$0.1 million.

Research and development expenses were \$8.7 million for the second quarter of 2017, compared to \$6.8 million for the same period in 2016. The increase was primarily attributable to \$2.2 million of expenses recorded in June due to the company's restructuring relating primarily to severance for the workforce reduction, EC1456 trial termination expenses and fixed asset impairment charges. Other increases included expenses for the EC1169 phase 1 trial, development of EC2629 and other pre-clinical and general research. These increases were partially offset by a decrease in non-cash stock compensation expense as a result of employee terminations since the second quarter of 2016.

General and administrative expenses were \$3.3 million for the second quarter of 2017, compared to \$7.4 million for the same period in 2016. The decrease was due to a decrease in compensation expense, including non-cash stock compensation expense and severance expense related to the resignation of our former Chief Executive Officer in June of 2016.

Cash, cash equivalents and investments were \$118.4 million at June 30, 2017, compared to \$154.6 million at June 30, 2016, and \$138.2 million at December 31, 2016.

### **Conference Call**

Endocyte management will host a conference call today at 4:30 p.m. EDT.

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

A live, listen-only webcast of the conference call may also be accessed by visiting the Investors & News section of the Endocyte website, [www.endocyte.com](http://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](http://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 treatment of cancer and other serious diseases. Endocyte uses its proprietary drug conjugation technology to create novel SMDCs and companion imaging agents for personalized targeted therapies. The company's SMDCs actively target receptors that are over-expressed on diseased cells relative to healthy cells. This targeted approach is designed to enable the treatment of patients with highly active drugs at greater doses, delivered more frequently and over longer periods of time than would be possible with the untargeted drug alone. The companion imaging agents are designed to identify patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment. In addition, the company continues to pursue applications of the SMDC platform and is working to bring assets toward clinical development in several areas, including EC2629, its dual-targeted DNA crosslinker drug that can attack both TAMs and cancer cells, and its CAR T-Cell SMDC adaptor platform. For additional information, please visit Endocyte's website at [www.endocyte.com](http://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, the successful completion of current and future clinical trials, the enrollment period for, and availability and reporting, of data from ongoing and future clinical trials, 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 those relating to future IND filings. 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 experience delays in the completion of its clinical trials (whether caused by competition, adverse events, patient enrollment rates, shortage of clinical trial materials, regulatory issues or other factors); risks that data from its 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's ability to capture value for the technology; 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.*

---

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

	<b>For the Three Months Ended June 30,</b>		<b>For the Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>
Collaboration revenue	\$ 13	\$ 13	\$ 25	\$ 25
Costs and expenses:				
Research and development	6,788	8,655	13,319	16,649
General and administrative	7,394	3,306	11,214	7,051
Total costs and expenses	<u>14,182</u>	<u>11,961</u>	<u>24,533</u>	<u>23,700</u>
Loss from operations	(14,169)	(11,948)	(24,508)	(23,675)
Interest income, net	208	234	397	469
Other expense, net	(1)	(30)	(4)	(27)
Net loss	<u>\$ (13,962)</u>	<u>\$ (11,744)</u>	<u>\$ (24,115)</u>	<u>\$ (23,233)</u>
Net loss per share - basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.28)</u>	<u>\$ (0.57)</u>	<u>\$ (0.55)</u>
Comprehensive loss	<u>\$ (13,897)</u>	<u>\$ (11,726)</u>	<u>\$ (23,940)</u>	<u>\$ (23,227)</u>
Weighted average number of common shares used in net loss per share calculation – basic and diluted	42,178,537	42,503,584	42,144,182	42,469,337

**Endocyte, Inc.**  
**Balance Sheets**  
(in thousands)

	<u>As of December 31, 2016</u>	<u>As of June 30, 2017</u> (unaudited)
Assets		
Cash, cash equivalents and investments	\$ 138,207	\$ 118,395
Other assets	5,287	3,545
Total assets	<u>\$ 143,494</u>	<u>\$ 121,940</u>
Liabilities and stockholders' equity		
Current liabilities	\$ 5,562	\$ 5,239
Deferred revenue and other liabilities, net of current portion	785	757
Total stockholders' equity	137,147	115,944
Total liabilities and stockholders' equity	<u>\$ 143,494</u>	<u>\$ 121,940</u>

---