EDGAR pro
by EDGAR Online

ENDOCYTE INC

FORM 8-K
(Current report filing)

Filed 03/10/17 for the Period Ending 03/10/17

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

Powered By EDGAR Online
http://www.edgar-online.com
© Copyright 2017, EDGAR Online, Inc. All Rights Reserved.
Distribution and use of this document restricted under EDGAR Online, Inc. Terms of Use.

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): March 10, 2017

Endocyte, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-35050	35-1969-140
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3000 Kent Avenue, Suite A1-100, West Lafayette, Indiana	47906
(Address of principal executive offices)	(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))

Item 2.02 Results of Operations and Financial Condition.

On March 10, 2017, Endocyte, Inc. (the "Company") announced its results of operations for the three months and full year ended December 31, 2016. A copy of the Company's earnings release is furnished herewith as Exhibit 99.1.

Item 7.01 Regulation FD Disclosure.

On March 10, 2017, the Company issued a press release announcing its plan to collaborate with Seattle Children's Research Institute and Dr. Michael Jensen for the development of Endocyte's SMDC platform in the chimeric antigen receptor T-cell (CAR T-cell) immunotherapy setting through the use of Endocyte's proprietary SMDC bi-specific adaptor molecules. A copy of the Company's press release is furnished herewith as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Earnings Release dated March 10, 2017

99.2 Press Release dated March 10, 2017

The information in this Current Report (including Exhibit 99.1 and Exhibit 99.2) 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 and Exhibit 99.2) 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.

March 10, 2017

By: /s/ Beth A. Taylor
Name: Beth A. Taylor
Title: *Vice President, Finance and Chief Accounting Officer*

Exhibit Index

Exhibit No.	Description
99.1	Earnings Release dated March 10, 2017
99.2	Press Release dated March 10, 2017

Exhibit 99.1

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

NEWS RELEASE

Endocyte Reports Fourth Quarter and Year End 2016 Financial Results and Provides Clinical and Pipeline Update

- Conference Call Today at 8:30 a.m. EST -

West Lafayette, Ind., March 10, 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 fourth quarter ending December 31, 2016, and provided a clinical and business update.

"We are pleased to report progress on several aspects of the business during the last several weeks," commented Mike Sherman, president and CEO at Endocyte. "The separately announced collaboration with Seattle Children's Research Institute and Dr. Michael Jensen, an innovator and thought leader in the field of chimeric antigen receptor T-cell (CAR T-cell) immunotherapies, is an indication of the promise of our technology and a reflection of our commitment to establishing partnerships intended to bring early stage programs to the clinic more rapidly and drive more value from our pipeline. Mike Andriole joining us as chief financial officer also adds significant experience and capacity to pursue value driving partnerships going forward."

"We also anticipate receiving additional clinical data on our lead assets, EC1169 and EC1456, during 2017 as we advance two additional agents toward the clinic," continued Mr. Sherman.

EC1169 (PSMA-tubulysin) Program Outline

- Currently enrolling patients in the expansion phase of the EC1169 trial in up to 50 second-line chemotherapy and up to 50 taxane-naïve metastatic castrate-resistant prostate cancer (mCRPC) patients at a maximum clinical once per week dose of 6.5 mg/m ^{2}
- Patients are scanned with Endcocyte's proprietary imaging agent, EC0652, to identify the presence of disease that expresses prostate- specific membrane antigen (PSMA)
- Primary endpoint of this expansion phase is radiographic progression-free survival (rPFS), measured at 5 months for taxane-naïve mCRPC patients and at 3 months for second-line chemotherapy patients
- Secondary endpoints which will provide earlier insight into drug activity include overall response rates as measured by response evaluation criteria in solid tumors (RECIST) 1.1 and prostate-specific antigen (PSA)
- Enrollment is not limited based on the results of the scan with EC0652 but primary endpoints of the trial are to be assessed in PSMA-positive patients

EC1456 (Folate-tubulysin) Program Outline

- Currently enrolling expansion cohort of up to 40 folate-receptor (FR) positive non-small cell lung cancer (NSCLC) patients, as determined by an etarfolatide scan, to receive the maximum clinical twice per week dose of 6.0 mg/m ^{2}
- Patients included in this expansion phase of the trial will have received first-line chemotherapy and may have also been treated with anti-PD-1 therapy
- Exploring a more frequent dosing schedule, four times per week, in indications that are typically FR-positive, such as ovarian and endometrial cancers
- Also conducting an ovarian cancer surgical study to assess various attributes of the drug release within targeted tumors

Upcoming Expected Milestones

- Safety and efficacy updates for both EC1169 and EC1456 ongoing clinical trials expected at the Annual Meeting of the American Society of Clinical Oncology in June, 2017
- Updated pre-clinical data for CAR T-cell program expected to be presented at a medical conference in the first half of 2017
- Expect to file Investigational New Drug (IND) application for EC2629 in mid 2017. EC2629 leverages a proprietary warhead with a dual mechanism of action: targeting both FR+ cancer cells and tumor associated macrophages (TAMs)
- Completion of pre-clinical evaluations for CAR T-cell program expected in second half of 2017
- Initiation of enrollment for EC2629 phase 1 trial expected in second half of 2017
- Pre-clinical preparatory work on EC2319 in anticipation of potential IND in 2018. EC2319 targets and disables activated macrophages which otherwise produce pro-inflammatory cytokines associated with chronic inflammatory disease

Fourth Quarter 2016 Financial Results

Endocyte reported a net loss of $11.1 million, or $0.26 per basic and diluted share, for the fourth quarter of 2016, compared to a net loss of $9.8 million, or $0.23 per basic and diluted share for the same period in 2015.

Research and development expenses were $8.2 million for the fourth quarter of 2016, compared to $6.4 million for the same period in 2015. The increase was primarily attributable to increases in expenses related to the EC1169 phase 1 trial, including drug manufacturing expenses.

General and administrative expenses were $3.1 million for the fourth quarter of 2016, compared to $3.5 million for the same period in 2015. The decrease was primarily attributable to a decrease in compensation expense, which was partially offset by an increase in expenses related to patent and recruiting fees.

Cash, cash equivalents and investments were $138.2 million at December 31, 2016, compared to $146.7 million at September 30, 2016, and $173.6 million at December 31, 2015.

Financial Expectations

The company anticipates its cash balance at the end of 2017 to be approximately $100 million.

About EC1456 and etarfolatide

EC1456 is an investigational therapeutic SMDC constructed of a high affinity FR-targeting ligand conjugated through a spacer and bioreleasable linker system to a potent cytotoxic microtubule inhibitor, TubBH. Patient FR-status is determined using the investigational companion imaging agent, etarfolatide.

About EC1169 and EC0652

EC1169 is an investigational therapeutic SMDC constructed of a high affinity prostate specific membrane antigen (PSMA)-targeting ligand conjugated through a bioreleasable linker system to a potent microtubule inhibitor, tubulysin B hydrazide (TubBH). Patient PSMA-status is determined using the investigational companion imaging agent, EC0652.

Conference Call

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

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 .

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 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. 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, 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. 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)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2015	2016	2015	2016
Collaboration revenue	$ 12	$ 12	$ 70	$ 70
Costs and expenses:				
Research and development	6,386	8,188	26,309	27,492
General and administrative	3,527	3,096	15,734	17,298
Total costs and expenses	9,913	11,284	42,043	44,790
Loss from operations	(9,901)	(11,272)	(41,973)	(44,720)
Interest income, net	162	232	652	861
Other income (expense), net	(55)	(25)	51	(29)
Net loss	$ (9,794)	$ (11,065)	$ (41,270)	$ (43,888)
Net loss per share - basic and diluted	$ (0.23)	$ (0.26)	$ (0.98)	$ (1.04)
Comprehensive loss	$ (9,897)	$ (11,137)	$ (41,205)	$ (43,849)
Weighted average number of common shares used in net loss – basic and diluted per share:	41,984,763	42,289,453	41,939,504	42,210,643

Endocyte, Inc.
Balance Sheets
(in thousands)

	As of December 31, 2015	As of December 31, 2016 (unaudited)
Assets		
Cash, cash equivalents and investments	$ 173,600	$ 138,207
Other assets	4,786	5,287
Total assets	$ 178,386	$ 143,494
Liabilities and stockholders' equity		
Current liabilities	$ 6,189	$ 5,562
Deferred revenue and other liabilities, net of current portion	851	785
Total stockholders' equity	171,346	137,147
Total liabilities and stockholders' equity	$ 178,386	$ 143,494

Exhibit 99.2

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

NEWS RELEASE

Endocyte and Seattle Children's Research Institute to Collaborate on Endocyte's Small Molecule Drug Conjugate Bi-Specific Adaptor Molecules for CAR T-cell Therapies

- Collaboration pairs leading SMDC technology with recognized CAR T-cell research expert -

- Plans to develop next generation CAR T-cell therapeutic platform with potential for improved safety and efficacy in solid tumor indications -

West Lafayette, Ind., March 10, 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 their plan to collaborate with Seattle Children's Research Institute and Dr. Michael Jensen for the development of Endocyte's SMDC platform in the chimeric antigen receptor T-cell (CAR T-cell) immunotherapy setting through the use of Endocyte's proprietary SMDC bi-specific adaptor molecules.

The aim of the research collaboration is to join Endocyte's SMDC bi-specific adaptor technology with the CAR T-cell immunotherapy research efforts at the Ben Towne Center for Childhood Cancer Research at Seattle Children's Research Institute, to move these potentially enabling technologies more quickly to patients in the clinic. Dr. Jensen, a recognized leader in the field of CAR T-cell research, is the director of Ben Towne Center for Childhood Cancer Research and the Janet and Jim Sinegal Endowed Chair in Pediatric Solid Tumor Research at Seattle Children's Research Institute, and a professor of hematology-oncology at the University of Washington School of Medicine.

"This partnership brings together Dr. Jensen's expertise in the discovery and development of CAR T-cell therapies and Endocyte's SMDC platform, with the aim of improving the efficacy and safety of CAR T-cell therapies and enabling them in solid tumor indications," said Mike Sherman, president and CEO of Endocyte. "Together, Seattle Children's Research Institute and Endocyte hope to make a meaningful difference in shaping the future of CAR T-cell therapies and offering an important new treatment option to cancer patients."

"This collaborative project with Endocyte represents a next-generation CAR T-cell therapeutic platform with exciting opportunities to target solid tumors," said Dr. Michael Jensen. "We have been impressed with the potential of Endocyte's bi-specific adaptor molecules, which enable the engineering of a single universal CAR T-cell that binds with very high affinity, potentially allowing us to address several key challenges of current therapies in this novel area of development."

Research and development activities under the collaboration will be led by Dr. Michael Jensen and Phil Low, PhD, Chief Scientific Officer at Endocyte and professor of chemistry and director of the Center for Drug Discovery at Purdue University.

About Endocyte's SMDC Bi-Specific Adaptors

Endocyte's SMDC bi-specific adaptors represent a novel approach that makes possible the engineering of a single universal CAR T-cell, designed to bind with high affinity to fluorescein isothiocyanate (FITC). This universal CAR T-cell can be specifically directed to cancer cells through the administration of a tumor targeted FITC-containing SMDC, known as a bi-specific adaptor, that acts to bridge the universal CAR T-cell with the cancer cells to cause localized T-cell activation. This technology may address or mitigate several challenges of current CAR T-cell therapies, such as i) the inability to control the rate of cytokine release and tumor lysis, ii) the absence of an "off switch" that can terminate cytotoxic activity when tumor eradication is complete, and iii) a requirement to generate a different CAR T-cell for each unique tumor antigen.

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. 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 relating to the company's development programs and upcoming milestones. 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 preclinical data may not be indicative of subsequent data when expanded to additional preclinical 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; estimates of the potential markets for its 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.