

ENDOCYTE INC

FORM 8-K (Current report filing)

Filed 06/02/17 for the Period Ending 05/23/17

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): May 23, 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.)
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3000 Kent Avenue, Suite A1-100, West Lafayette, Indiana (Address of principal executive offices)	47906 (Zip Code)
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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 2.05 Costs Associated with Exit or Disposal Activities.

Endocyte, Inc. (the “Company”) is implementing a strategic restructuring to focus on an updated business plan. Based on safety and efficacy data, the Company is stopping enrollment in the EC1456 trial, but will continue to enroll a small number of patients in the EC1456 ovarian cancer surgical study to gain additional insight to inform the development of future small molecule drug conjugates (SMDCs). Based on an interim assessment to confirm drug activity, the Company will continue to enroll patients in the EC1169 phase 1b trial for taxane-exposed metastatic castration-resistant prostate cancer. For the second EC1169 arm, the Company will stop enrollment of taxane-naïve patients as the efficacy signals were less clear. The Company plans to continue development of the next-generation chimeric antigen receptor T-cell (CAR T-cell) SMDC adaptor platform in collaboration with leading experts in the field at Seattle Children’s Research Institute, and the dual-targeted DNA crosslinker drug EC2629. The Company continues to refine and update its business plan and is committed to productive investment of capital.

The Company’s Board of Directors committed to this course of action on May 23, 2017, and the Company informed affected employees on June 2, 2017. As part of this strategic restructuring, the Company’s workforce will be reduced to 47 employees, which is an approximate 40% reduction across the organization. The Company expects to establish a severance program for employees affected by the reduction of personnel and to substantially complete the reduction in the third quarter of 2017. The Company currently anticipates incurring total restructuring costs related to the strategic restructuring of approximately \$2.4 million, which includes severance, benefits and related costs of approximately \$1.1 million, fixed asset impairment charges of approximately \$0.3 million, and clinical trial termination charges and other charges of approximately \$1.0 million. Of this \$2.4 million, approximately \$2.0 million is expected to consist of future cash expenditures and is expected to be paid before the end of 2017. The Company is continuing to review the potential impact of the restructuring, and is unable to estimate any additional restructuring costs or charges at this time. If the Company subsequently determines that it will incur additional significant costs and restructuring charges, it will amend this Current Report on Form 8-K to disclose such information.

As permitted by an interpretation of the Securities and Exchange Commission, this Form 8-K is being timely filed on the date on which the employees affected by the strategic restructuring were informed of their termination.

ITEM 2.06 Material Impairments.

The information required by this Item 2.06 is contained in Item 2.05 above and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release issued on June 2, 2017

Cautionary Note on Forward-Looking Statements

Certain of the statements made in this report are forward looking, such as those, among others, relating to future spending, future cash balances, reduction in personnel, expected amounts and types of costs, charges and payments related to the strategic restructuring, other expected impacts of the strategic restructuring, 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.

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.

June 2, 2017

By: /s/ Beth A. Taylor

Name: Beth A. Taylor

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

Exhibit Index

Exhibit No.	Description
99.1	Press release issued on June 2, 2017

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

NEWS RELEASE

Endocyte Announces Clinical Updates for EC1456 and EC1169

- *Company Continuing EC1169 Program in Taxane-Exposed Patients, but Ending Clinical Development of EC1456 and of EC1169 in Taxane-Naïve Patients -*
- *Refocusing Efforts on Chimeric Antigen Receptor T-cell (CAR T-cell) and Dual-Targeted DNA Crosslinker Drug EC2629 Programs -*
- *Restructuring to Reduce Workforce by Approximately 40%; Will Maintain Core Competencies and Preserve Capital for Highest Priority Programs -*
- *Conference Call Today at 8:30 a.m. EDT -*

West Lafayette, Ind., June 2, 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 updates on clinical development for EC1456, its folate receptor-targeted tubulysin cancer therapy, and EC1169, its prostate-specific membrane antigen targeted (PSMA-targeted) tubulysin prostate cancer therapy.

Endocyte will narrow the EC1169 development program to focus only on the cohort of taxane-exposed, metastatic castration-resistant prostate cancer (mCRPC) patients, for which a top-line efficacy assessment of the expansion phase of this phase 1 trial is expected before the end of 2017. An interim assessment confirmed clinical activity of the drug in the taxane-exposed cohort with a partial response in one patient, stable disease in other patients, and other markers of activity. Endocyte believes EC1169 may have benefit in taxane-exposed patients, with more advanced disease, where upregulation of PSMA increases with prior treatments. Endocyte will stop enrollment of taxane-naïve mCRPC patients in the EC1169 trial.

In addition, the company plans to stop enrollment in the EC1456 trial, where a careful assessment in folate receptor-positive (FR-positive) disease across multiple cohorts of patients and multiple dosing schedules did not yield the level of clinical activity necessary to support continued advancement of this agent. However, enrollment of a small number of patients in the EC1456 ovarian cancer surgical study will continue in order to inform other SMDC programs in development. Preliminary data to-date from the ovarian surgical study provides evidence that patients with FR-positive disease are being successfully identified with the use of the etarfolatide imaging agent, but the intratumoral levels of the EC1456 drug payload may be lower than predicted by pre-clinical models.

“Endocyte is a data-driven company, and we are committed to the disciplined management of clinical programs as the science guides us,” said Mike Sherman, president and CEO at Endocyte. “Recently gained insight into the safety and efficacy of EC1169 and EC1456, coupled with our commitment to the productive investment of capital, has led us to refocus efforts on our most promising programs, which include our CAR T-cell SMDC adaptor platform, our dual-targeted DNA crosslinker drug EC2629, and the cohort of taxane-exposed patients receiving EC1169.”

Endocyte is advancing its work with Seattle Children’s Research Institute aimed at bringing its CAR T-cell bi-specific adaptor molecule to the clinic in 2018. In addition, the company plans to file its IND for EC2629 in mid-2017, which includes a potent DNA-targeted warhead with clinically proven activity. To Endocyte’s knowledge, this is the first drug candidate designed to simultaneously target both tumor cells and tumor associated macrophages (TAMs), which contribute to disease progression by interfering with natural anti-tumor immune responses.

Endocyte also announced today plans to reduce its workforce by approximately 40 percent in order to better focus its resources on the company’s highest value opportunities, while maintaining key capabilities.

“As we refocus our clinical development efforts, we are also aligning our investments and resources to advance our most compelling pipeline programs to key inflection points,” added Sherman. “We are very grateful for all the contributions over the years from our dedicated, talented team of employees, who have devoted so much of themselves towards helping advance our efforts to bring our innovative, targeted therapies to patients with cancer and other serious diseases. We’ll be working closely with those affected by the restructuring to support them through this difficult but necessary transition.”

Endocyte anticipates one-time charges of approximately \$2.4 million related to termination benefits and the accelerated closure of the EC1456 trial. As a result of this restructuring, the company is revising its guidance for 2017 and now expects its cash balance at the end of 2017 to be approximately \$105 million, with a more substantial positive impact from the restructuring beginning in 2018.

About EC1169 and the Phase 1 Trial

EC1169 is an investigational therapeutic SMDC constructed of a high affinity 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. EC1169 and EC0652 are currently being evaluated in a phase 1b study in up to 50 taxane-exposed mCRPC patients at a maximum clinical EC1169 dose of 6.5 mg/m². Endocyte is stopping enrollment of taxane-naïve mCRPC patients (ClinicalTrials.gov Identifier: NCT02202447).

The open-label, multicenter, non-randomized, study is divided into two parts. The first part of the study, now complete, was designed to determine the maximum clinical dose and recommended Phase 2 dose of EC1169 in patients with mCRPC.

Endocyte is currently enrolling the second part of the study which is designed to evaluate the safety and efficacy of EC1169 in taxane-exposed patients, with a primary study endpoint of radiographic progression free survival in patients selected as PSMA-positive. The trial is expected to complete enrollment in Q3 2017 with a more mature endpoint assessment by year-end.

About EC1456 and the Phase 1 Trial

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.

Endocyte completed the dose escalation portion of the study designed to determine the maximum clinical dose for multiple dosing schedules and is stopping enrollment of the phase 1b study which was evaluating EC1456 at a dose of 6.0mg/m² twice weekly (BIW) in up to 40 FR-positive non-small cell lung cancer (NSCLC) patients (as determined by an etarfolatide scan).

Endocyte is currently conducting an ovarian cancer surgical study to characterize etarfolatide imaging and intratumoral EC1456 through a multifaceted analysis of collected tissue samples after administration of the drug.

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 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, reduction in personnel, expected impact from the restructuring, expected charges related to the restructuring, 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 and regulatory authorizations 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.
