ENDOCYTE INC

FORM 8-K
(Current report filing)

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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): November 6, 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))

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 November 6, 2017, Endocyte, Inc. (the "Company") announced its results of operations for the three months ended September 30, 2017. A copy of the Company's earnings release is furnished herewith as Exhibit 99.1.

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.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Index

Exhibit No.	**Description**
99.1	Press release issued on November 6, 2017

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.

November 6, 2017

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

Exhibit 99.1

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

NEWS RELEASE

Endocyte Reports Third Quarter Financial Results

- Plans to Initiate Phase 3 Registration for ^{177}Lu-PSMA-617 Accelerated by Radiomedix Agreement to Transfer Active U.S. Investigational New Drug Application (IND) to Endocyte -

- The University of Sydney and ANZUP Cancer Trial Group Set to Initiate Trial of ^{177}Lu-PSMA-617 versus Cabazitaxel Under Agreement with Endocyte -

- CAR T-Cell Program on Schedule to Initiate Clinical Trial in Osteosarcoma in 2018 -

- Conference Call Today at 4:30 p.m. EST -

West Lafayette, IN., Nov. 6, 2017 – Endocyte, Inc. (NASDAQ Global Market: ECYT), a biopharmaceutical company developing targeted therapeutics for personalized cancer treatment, today announced financial results for the third quarter ending Sept. 30, 2017, and provided an update on its recently in-licensed lead program, PSMA-617.

"The third quarter was transformative for Endocyte, as we accelerated our path to commercialization by obtaining worldwide rights to develop ^{177}Lu-PSMA-617, a potentially first-in-class radioligand therapeutic (RLT) and $1 billion revenue opportunity, addressing both bone and soft tissue disease in prostate cancer patients. In the weeks since closing that transaction, we've made tremendous progress advancing the development of this promising therapy towards phase 3 initiation in the first half of next year," said Mike Sherman, president and CEO of Endocyte. "Data presented at the ESMO 2017 Congress from the Peter MacCallum Cancer Center-sponsored ^{177}Lu-PSMA-617 trial in metastatic castration-resistant prostate cancer (mCRPC) patients demonstrated promising response rates, and we expect updated results from the trial expansion to be presented in 2018."

Mr. Sherman continued, "With our new focus on RLTs in prostate cancer and our collaboration with Seattle Children's Research Institute to develop our chimeric antigen receptor t-cell (CAR T-cell) therapy in pediatric osteosarcoma, we've positioned Endocyte in two of the most promising fields of emerging cancer therapy, the values of which have been highlighted recently by multi-billion dollar transactions."

New Agreements Accelerate and Expand ^{177}Lu-PSMA-617 Development

Endocyte and Radiomedix, a biotechnology company focused on innovative targeted radiopharmaceuticals for diagnosis, monitoring and therapy of cancer, announced today that the companies have entered into an agreement that enables the transfer of a U.S. IND of ^{177}Lu-PSMA-617 from the current sponsor, Radiomedix, to Endocyte. This transfer is expected to be formally acknowledged by the U.S. FDA in the coming weeks and will accelerate Endocyte's end-of-phase 2 meeting with the agency to confirm Endocyte's phase 3 design and protocol for ^{177}Lu-PSMA-617.

In addition, under a three-party agreement among Endocyte, the University of Sydney and ANZUP, a cooperative cancer trials group operating in Australia and New Zealand pursuing research in genito-urinary malignancies, ANZUP will sponsor and undertake jointly with the University a randomized phase 2 multi-center TheraP trial of ^{177}Lu-PSMA-617 versus cabazitaxel in 200 mCRPC patients. Under the three-party agreement, Endocyte will provide the PSMA-617 precursor molecule and modest financial support for the trial. Endocyte will have access to data generated from the trial, which is a potentially important supportive trial for future regulatory submissions. The primary financial obligations of the trial, along with labeling PSMA-617 with Lutetium-177, will be the responsibility of the University and ANZUP.

Peter MacCallum Cancer Center-Sponsored ^{177}Lu-PSMA-617 Trial

At the 2017 ESMO conference in September, Dr. Michael Hofman of the Peter MacCallum Cancer Center in Melbourne, Australia presented the results of an open-label, single-arm, non-randomized trial of ^{177}Lu-PSMA-617. Thirty mCRPC patients were treated with up to four cycles and doses of 4-8 GBq. Primary endpoints included safety and efficacy as defined by prostate specific antigen (PSA) response, quality of life, and imaging response. As previously announced, the results showed a 57% PSA response rate (>50% reduction) and 71% interim response rate in soft tissue lesions (as measured by RECIST criteria) in patients who had previously failed conventional therapies such as docetaxel, cabazitaxel, enzalutamide and abiraterone. Median overall survival was 12.7 months. The drug was well-tolerated, with a low rate of adverse effects and no renal toxicity. Significantly improved quality of life scores and reduction in pain scores were recorded in 37% and 43% of patients, respectively. This trial has subsequently been expanded to 50 subjects from the original 30, with updated results expected to be presented in 2018.

CAR T-Cell Development Remains on Schedule

In September 2017, Endocyte presented data on its adaptor controlled CAR T-cell platform at the 2017 CAR-TCR Summit, further demonstrating how its novel CAR-T therapy controls T-cell activity to enhance both safety and efficacy. Dr. Michael Jensen of Seattle Children's Research Institute will lead the clinical evaluation of Endocyte's first adaptor controlled CAR T-cell therapy in patients with folate-receptor positive osteosarcoma, with pre-clinical evaluations expected to be completed before the end of this year, in anticipation of a potential IND filing in 2018. Multiple additional adaptor molecules designed to be directed to distinct tumor targets including, potentially, cholecystokinin-2 receptor (CCK2R), neurokinin-1 receptor (NK1R) and others, are in development through the company's collaboration with Purdue University.

Upcoming Expected Milestones

- Australian TheraP trial first patient visit (Dec 2017)
- Expected initiation of US registration trial of ^{177}Lu-PSMA-617 in mCRPC first patient visit (1H 2018)
- Mature full 50-patient data readout, including overall survival, of investigator initiated trial at Peter MacCallum Cancer Centre in Melbourne, Australia (2H 2018)
- Publications on other ongoing investigator initiated clinical trials of ^{177}Lu-PSMA-617 in prostate cancer patients (2018)
- CAR-T phase 1 first patient visit in osteosarcoma and potential proof of concept (2H 2018)

Third Quarter 2017 Financial Results

Endocyte reported a net loss of $23.3 million, or $0.55 per basic and diluted share, for the third quarter of 2017, compared to a net loss of $8.7 million, or $0.21 per basic and diluted share for the same period in 2016.

In September 2017, the Company entered into a development and license agreement with ABX GmbH (the “License Agreement”) that grants the Company exclusive worldwide rights to develop and commercialize PSMA-617, including the product candidate known as ^{177}Lu-PSMA-617, an RLT that targets prostate-specific membrane antigen (PSMA). The Company recorded $16.5 million of acquired in-process research and development (“IPR&D”) expenses related to the License Agreement for the three months ended September 30, 2017 consisting of the following:

- $12.0 million related to an upfront payment to ABX;
- $3.8 million related to the fair value of common stock and warrant shares issued in the transaction; and
- $0.7 million of acquisition costs consisting primarily of legal and professional fees.

Research and development expenses were $4.1 million for the third quarter of 2017, compared to $6.0 million for the same period in 2016. The decrease was primarily attributable to: a decrease of $1.1 million in compensation expense as a result of employee terminations since September 30, 2016, including those resulting from the company’s restructuring in June 2017; a decrease in expenses related to trial and manufacturing costs for EC1456; decreases in expenses related to pre-clinical work and general research, including the development of EC2629; and a decrease in manufacturing expense for EC1169. These decreases were partially offset by an increase in expenses related to the EC1169 phase 1b trial.

General and administrative expenses were $3.0 million for the third quarter of 2017, compared to $3.0 million for the same period in 2016. Expenses remained consistent compared to the prior year, as an increase in expenses related to legal and professional fees were offset by a decrease in expenses related to stock compensation expense due to employee terminations as a result of the company's restructuring activities in June 2017.

Cash, cash equivalents and investments were $103.1 million at September 30, 2017, compared to $118.4 million at June 30, 2017, and $138.2 million at December 31, 2016.

Financial Expectations

The company anticipates its cash, cash equivalents and investments balance at the end of 2017 to be above $90 million.

Conference Call

Endocyte management will host a conference call today at 4:30 p.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. Endocyte uses drug conjugation technology to create novel therapeutics and companion imaging agents for personalized targeted therapies. The company's agents actively target receptors that are over-expressed on diseased cells relative to healthy cells, such as prostate-specific membrane antigen (PSMA) in prostate cancer. This targeted approach is designed to safely enable the delivery of highly potent drug payloads. 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, future use of capital, the timing of initiation 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 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. 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 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'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 September 30,		For the Nine Months Ended September 30,	
	2016	2017	2016	2017
Collaboration revenue	$ 33	$ 33	$ 58	$ 58
Costs and expenses:				
Research and development	5,985	4,090	19,304	20,739
General and administrative	2,988	3,011	14,202	10,062
Acquired in-process research and development	—	16,493	—	16,493
Total operating expenses	8,973	23,594	33,506	47,294
Loss from operations	(8,940)	(23,561)	(33,448)	(47,236)
Interest income, net	232	265	629	734
Other income (expense), net	—	29	(4)	2
Net loss	$ (8,708)	$ (23,267)	$ (32,823)	$ (46,500)
Net loss per share - basic and diluted	$ (0.21)	$ (0.55)	$ (0.78)	$ (1.09)
Comprehensive loss	$ (8,772)	$ (23,237)	$ (32,712)	$ (46,463)
Weighted average number of common shares used in net loss per share calculation – basic and diluted	42,263,311	42,636,567	42,184,182	42,525,693

Endocyte, Inc.
Balance Sheets
(in thousands)

	As of December 31, 2016	As of September 30, 2017 (unaudited)
Assets		
Cash, cash equivalents and investments	$ 138,207	$ 103,080
Other assets	5,287	3,765
Total assets	$ 143,494	$ 106,845
Liabilities and stockholders' equity		
Current liabilities	$ 5,562	$ 4,347
Deferred revenue and other liabilities, net of current portion	785	745
Total stockholders' equity	137,147	101,753
Total liabilities and stockholders' equity	$ 143,494	$ 106,845