ENDOCYTE INC
Form 8-K
September 10, 2018
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): September 10, 2018

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 7.01Regulation FD Disclosure

On September 10, 2018, Endocyte, Inc. (the “Company”) issued a press release announcing that, following a meeting with the U.S. Food and Drug Administration (“FDA”), it was determined that radiographic progression free survival (“rPFS”) is an appropriate efficacy endpoint in the Company’s ongoing phase 3 VISION trial to support the submission of a New Drug Application (“NDA”) for full FDA approval of 177Lu-PSMA-617 for the treatment of metastatic castration-resistant prostate cancer. The updated trial protocol will reflect this determination on rPFS while retaining the final, fully powered overall survival (“OS”) analysis. The Company expects to complete the analysis of rPFS before the end of 2019 and to complete the analysis of OS near the end of 2020.

Under the updated VISION trial design, the two interim assessments previously planned at 50% and 70% of OS events will be replaced with a single assessment of rPFS. This assessment is expected to occur at approximately the same time that the first interim OS assessment would have occurred under the prior trial design and shortly after the time the trial is fully enrolled. If 177Lu-PSMA-617 meets the primary endpoint in the rPFS assessment, no unexpected safety issues arise, and it demonstrates no detriment in OS relative to the control arm, the Company intends to submit an NDA to seek full approval in the United States. The rPFS analysis will include approximately 450 rPFS events. Regardless of the outcome of the rPFS assessment, the Company intends to continue to follow patients in the VISION trial in order to assess the final OS alternative primary endpoint. An efficacy analysis of OS will be conducted at approximately 490 events. Other aspects of the VISION trial design, including patient treatment and assessments, trial size, overall duration, and follow up remain unchanged. Secondary endpoints include response evaluation criteria in solid tumors (“RECIST”) response and time to first symptomatic skeletal event.

The information contained in this Item 7.01 and in Item 9.01 of this Current Report (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

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, 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. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof. 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, 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 the Company is contained in the Company's periodic reports filed with the Securities and Exchange Commission. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required under applicable law.

ITEM 9.01Financial Statements and Exhibits.

A copy of the Company's press release is furnished, but not filed, as Exhibit 99.1 hereto.

(d) Exhibits:

Exhibit Index

Exhibit No.	Exhibit
99.1	Press release issued on September 10, 2018

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.

September 10, 2018 By: /s/ Beth A. Taylor
Name: Beth A. Taylor
Title: Vice President of Finance and Chief Accounting Officer