

BIOTIME INC
Form 8-K
July 31, 2014

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): **July 31, 2014**

BioTime, Inc.

(Exact name of registrant as specified in its charter)

| | | |
|---|--------------------------|--------------------------------------|
| California | 1-12830 | 94-3127919 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

1301 Harbor Bay Parkway
Alameda, California 94502
(Address of principal executive offices)

(510) 521-3390
(Registrant's telephone number, including area code)

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))
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Forward-Looking Statements

Any statements that are not historical fact (including, but not limited to statements that contain words such as “may,” “will,” “believes,” “plans,” “intends,” “anticipates,” “expects,” “estimates”) should also be considered to be forward-looking statements. Additional factors that could cause actual results to differ materially from the results anticipated in these forward-looking statements are contained in BioTime’s periodic reports filed with the SEC under the heading “Risk Factors” and other filings that BioTime may make with the Securities and Exchange Commission. Undue reliance should not be placed on these forward-looking statements which speak only as of the date they are made, and the facts and assumptions underlying these statements may change. Except as required by law, BioTime disclaims any intent or obligation to update these forward-looking statements.

Section 8 – Other Events

Item 8.01 Other Events

Our subsidiary OncoCyte Corporation has expanded the clinical development of its urine-based bladder cancer diagnostic test by initiating a multi-site clinical trial. The trial, which will involve up to 1,200 patient samples obtained from at least four large urology clinics located throughout the United States, has received Institutional Review Board (IRB) approval at multiple sites and should begin enrolling patients within the next week. OncoCyte’s initial clinical study of its bladder cancer diagnostic test began in January and involves pathology specimens being collected at a leading medical institution with an international reputation for excellence and discovery. The multi-site clinical trial, which has been initiated in part due to positive interim data from the ongoing study in pathology specimens, is designed to expand the potential use of the *PanC-Dx*TM bladder cancer test beyond pathology laboratories and into urologic practices at the point of cystoscopy. Cystoscopy along with urine cytopathology, are the standard methods utilized for bladder cancer screening and diagnosis. The multi-site clinical trial should be completed within 12 months.

The goal of the current clinical trial is to compare the performance of OncoCyte’s proprietary *PanC-Dx*TM bladder cancer markers to the performance of cystoscopy. Investigators in the trial are collecting urine samples from patients undergoing cystoscopy for the diagnosis of either primary or recurrent bladder cancer. Cystoscopy and biopsy results will be compared with the results of OncoCyte’s proprietary diagnostic test panel in determining the overall performance of the *PanC-Dx*TM markers. *PanC-Dx*TM is a class of non-invasive cancer diagnostics based on OncoCyte’s proprietary set of cancer markers discovered by OncoCyte scientists through an analysis of broad gene expression patterns in numerous cancer types. The performance of the test in detecting the absence, presence, or progression of urothelial carcinoma in patients will determine the specific nature of the bladder cancer diagnostic to be developed and the regulatory approval pathway that OncoCyte will pursue.

Urothelial carcinoma (UC) constitutes more than 90% of bladder cancers in the Americas, Europe and Asia. Although most patients with bladder cancer can be treated with organ-sparing chemotherapy, UC has a relapse rate of nearly 70% and can progress to invasive, metastatic, and lethal disease. The regular surveillance and treatment of recurrent disease from the time of diagnosis for the remainder of a patient’s life makes UC the most costly malignancy on a per patient basis. The problem is amplified because the two standard methods for surveillance - microscopic assessment of urinary cytology specimens and bladder cystoscopy— possess significant limitations with respect to both performance and cost. Although urine cytology does have a very high positive predictive value (low false positive rate), it has a low negative predictive value and a high indeterminate rate. Patients who have indeterminate urine cytology results commonly undergo cystoscopy, which is painful, time consuming, costly, and unnecessary in many cases since a neoplasm is often not present. In UC, as in virtually all other cancers, earlier and more accurate diagnosis, including diagnosis of disease recurrence, is generally associated with better outcomes and lower cost.

Overall markets for bladder cancer diagnostics are large and growing. Based on National Cancer Institute statistics released in 2012, it was estimated that in 2013 over 72,000 new cases of bladder cancer would occur in the United States and a total of over 550,000 men and women alive would have a history of bladder cancer and be subject to recurrence surveillance testing using cystoscopy or urine cytology.

Section 9 - Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|-----------------------------------|
| 99.1 | Press Release Dated July 31, 2014 |

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.

BIOTIME, INC.

Date: July 31, 2014 By: /s/ Robert W. Peabody
Senior Vice President,
Chief Operating Officer,
Chief Financial Officer

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|-----------------------------------|
| 99.1 | Press Release Dated July 31, 2014 |