

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): **April 20, 2015**

BioTime, Inc.

(Exact name of registrant as specified in its charter)

California

(State or other jurisdiction
of incorporation)

1-12830

(Commission File Number)

94-3127919

(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 Securities and Exchange Commission (“SEC”) under the heading “Risk Factors” and other filings that BioTime may make with the SEC. 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

On April 20, 2015, we and our subsidiary OncoCyte Corporation issued the press releases included as Exhibits 99.1 and 99.2 to this report, which are incorporated by reference, concerning data from certain clinical studies of OncoCyte’s *PanC-Dx*TM class of proprietary, non-invasive cancer diagnostic tests, including one for detecting the most common type of bladder cancer, urothelial carcinoma, and one for detecting other types of human cancers, including breast cancer.

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 April 20, 2015
99.2	Press release dated April 20, 2015

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: April 20, 2015

By: /s/ Michael D. West
Chief Executive Officer

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated April 20, 2015
99.2	Press release dated April 20, 2015

Positive Clinical Results of OncoCyte's *PanC-Dx*TM Diagnostic Test Demonstrate High Level of Sensitivity and Specificity in Non-Invasive Detection of Bladder Cancer

Data Presented at American Association for Cancer Research 2015 Annual Meeting

ALAMEDA, Calif.--(BUSINESS WIRE)--April 20, 2015--BioTime, Inc. (NYSE MKT:BTX) and its subsidiary OncoCyte Corporation today announced positive clinical results of *PanC-Dx*TM, OncoCyte's class of proprietary, non-invasive cancer diagnostic tests, in detecting the most common type of bladder cancer, urothelial carcinoma (UC). Karen B. Chapman, PhD, Vice President of Research at OncoCyte, presented the results from two prospective clinical studies of *PanC-Dx*TM at the American Association for Cancer Research (AACR) Annual Meeting during a poster presentation from 1:00 PM - 5:00 PM EDT on Sunday, April 19, 2015.

The first clinical study was conducted by OncoCyte in collaboration with investigators in the Department of Pathology at Johns Hopkins University School of Medicine led by Matthew T. Olson, M.D., Assistant Professor and Associate Director of the Division of Cytopathology in the Department of Pathology at Johns Hopkins University School of Medicine and principal investigator of the trial, and Dorothy Rosenthal, M.D., Professor of Pathology, Oncology and Gynecology/Obstetrics at Johns Hopkins University School of Medicine and collaborator on the study.

Clinical investigation involved collection of 90 urine samples from patients undergoing urine cytology for the diagnosis of either primary or recurrent bladder cancer. Patient urine samples were assessed microscopically for the presence of cancer cells using the current standard-of-care method of cytopathology; in parallel, study investigators analyzed the urine samples for gene expression. A panel of 43 gene expression biomarkers that distinguishes UC from non-cancerous conditions was identified.

Study investigators then investigated the performance the 43-marker panel derived from the first clinical study using a set of 195 urine samples obtained from a second, large ongoing clinical study at multiple urology clinics in the United States. Investigators in the trial are collecting urine samples from patients undergoing cystoscopy for the diagnosis of either primary or recurrent bladder cancer. A gene expression classifier was developed with the goal of distinguishing between UC and benign conditions. Performance of the classifier was evaluated using several cross-validation criteria, including Receiver Operating Characteristic (ROC) area under the curve (AUC) analysis, yielding an AUC of 0.91 (sensitivity of 90% with a specificity of 82.5%). Optimal performance of the classifier was achieved using only two markers.

“The encouraging results to date validate our confidence that the *PanC-Dx*TM diagnostic technology can be used to develop a potentially accurate and more convenient alternative for detecting bladder cancer or its recurrence, compared to currently used costly and invasive diagnostic procedures,” said Joseph Wagner, PhD, OncoCyte's Chief Executive Officer. “Our second bladder cancer clinical trial of up to 1,400 patient samples is approximately half-way complete in terms of patient enrollment and should be completed by the end of 2015. This study will further refine and validate *PanC-Dx*TM, as well as establish initial clinical utility data. Although further clinical studies may be necessary for approval by the U.S. Food and Drug Administration, the data from these two studies could enable us to advance into the commercialization phase of our bladder cancer diagnostic test.”

Overall markets for bladder cancer diagnostics are large and growing. Based on National Cancer Institute statistics, it was estimated that in 2015 over 74,000 new cases of bladder cancer would occur in the United States and a total of over 500,000 men and women alive would have a history of bladder cancer and be subject to recurrence surveillance testing using cystoscopy or urine cytology. Bladder cancer has the highest recurrence rate of any major type of cancer; recurrence surveillance testing is strongly recommended and widely performed.

About OncoCyte Corporation

OncoCyte, a majority-owned subsidiary of BioTime, Inc., is developing novel products for the diagnosis and treatment of cancer in order to improve the quality and length of life of cancer patients. Based on large unmet need, market size, and data generated thus far from patient sample screening, OncoCyte is initially focusing its efforts on developing *PanC-Dx*[™] diagnostic products for use in detecting breast, bladder, and lung cancers. *PanC-Dx*[™] is a class of non-invasive cancer diagnostics based on a proprietary set of cancer markers characterized, in part, by broad gene expression patterns in numerous cancer types. The *PanC-Dx*[™] biomarkers were discovered as a result of ongoing research within OncoCyte and BioTime on the gene expression patterns associated with embryonic development. This research has demonstrated that many of the same genes associated with normal growth during embryonic development are abnormally reactivated by cancer cells. These genes regulate such diverse processes as cell proliferation, cell migration and blood vessel formation. Many of these genes have not been previously associated with cancer. Moreover, expression of a large subset of these genes is conserved across numerous cancer types (e.g. cancers of the breast, colon, ovaries, etc.), suggesting these genes may control fundamental processes during cancer growth and progression. In addition to their potential value in developing diagnostic biomarkers, an understanding of the pattern of expression of these genes may also enable the development of powerful new cancer therapeutics that target rapidly proliferating cancer cells.

About BioTime

BioTime, Inc., a pioneer in regenerative medicine, is a clinical-stage biotechnology company. BioTime and its subsidiaries are leveraging their industry-leading experience in pluripotent stem cell technology and a broad intellectual property portfolio to facilitate the development and use of cell-based therapies and gene marker-based molecular diagnostics for major diseases and degenerative conditions for which there presently are no cures. The lead clinical programs of BioTime and its subsidiaries include: *OpRegen*[®], currently in a Phase I/IIa trial for the treatment of the dry form of age-related macular degeneration; *AST-OPC1*, currently in a Phase I/IIa trial for spinal cord injuries; *Renevia*[™], currently in a pivotal trial in Europe as an injectable matrix for the engraftment of transplanted cells to treat HIV-related lipodystrophy; and *PanC-Dx*[™] cancer diagnostics, which are completing initial clinical studies for bladder, breast, and lung cancer. *AST-VAC2*, a cancer vaccine, is in the pre-clinical trial stage.

BioTime's subsidiaries include: publicly-traded Asterias Biotherapeutics, Inc. (NYSE MKT: AST), developing pluripotent stem cell-based therapies in neurology and oncology, including *AST-OPC1* and *AST-VAC2*; Cell Cure Neurosciences Ltd., developing stem cell-based therapies for retinal and neurological disorders, including *OpRegen*[®]; OncoCyte Corporation, developing *PanC-Dx*[™] cancer diagnostics; LifeMap Sciences, Inc., developing and marketing an integrated on-line database resource for biomedical and stem cell research; LifeMap Solutions, Inc., a subsidiary of LifeMap Sciences, developing mobile health (mHealth) products; ES Cell International Pte Ltd, which has developed cGMP compliant human embryonic stem cell lines that are being marketed by BioTime for research purposes under the ESI BIO branding program; OrthoCyte Corporation, developing therapies to treat orthopedic disorders, diseases and injuries; and ReCyte Therapeutics, Inc., developing therapies to treat a variety of cardiovascular and related ischemic disorders.

BioTime common stock is traded on the NYSE MKT under the symbol BTX. For more information, please visit www.biotimeinc.com or connect with the company on Twitter, LinkedIn, Facebook, YouTube, and Google+.

FORWARD-LOOKING STATEMENTS

Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for BioTime and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates”) should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the business of BioTime and its subsidiaries, particularly those mentioned in the cautionary statements found in BioTime's Securities and Exchange Commission filings. BioTime disclaims any intent or obligation to update these forward-looking statements.

To receive ongoing BioTime corporate communications, please click on the following link to join our email alert list: <http://news.biotimeinc.com>

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OncoCyte Announces Initial Data From Ongoing Clinical Study of Collagen Type X as a Marker and Potential Diagnostic for Breast Cancer and Other Types of Human Cancers

Data Presented at American Association for Cancer Research 2015 Annual Meeting

ALAMEDA, Calif.--(BUSINESS WIRE)--April 20, 2015--BioTime, Inc. (NYSE MKT:BTX) and its subsidiary OncoCyte Corporation today announced initial data from a large, prospective clinical study that showed the potential of *PanC-Dx*TM, OncoCyte's non-invasive diagnostic technology based on its proprietary set of cancer markers, as a non-invasive, blood-based diagnostic test to screen for multiple types of human cancers, including breast cancer. The early data showed the utility of the protein Collagen Type X (COL10A1) in distinguishing patients with malignant breast lesions from those with negative findings. The clinical data was presented by Maria Prendes, PhD, Director of Manufacturing at OncoCyte, at the American Association for Cancer Research (AACR) Annual Meeting during a poster presentation from 8:00 AM -12:00 PM EDT on Monday, April 20, 2015.

The controlled study, initiated at Scottsdale Medical Imaging Laboratories in Scottsdale, AZ, is ongoing and has nearly completed enrollment of over 600 patients. The goal of this study is to assess the performance of *PanC-Dx*TM in discriminating patients with malignant breast lesions from those with negative findings or benign findings. Study investigators are collecting blood samples from patients undergoing screening or diagnostic mammography. Patient blood samples are being assessed for levels of OncoCyte's *PanC-Dx*TM markers, including the concentration of the protein COL10A1, using proprietary assays and the results are compared to radiological and pathology findings. Expression of the gene *COL10A1* at an mRNA level has been shown in past studies to be significantly elevated in multiple and diverse malignant tumor types including cancers of the breast, stomach, colon, lung, bladder, pancreas, and ovaries. In addition, the protein was shown to be specifically localized within tumor vasculature.

Early data showed that *PanC-Dx*TM identified a mean concentration of COL10A1 protein in sera of breast cancer patients (n=33) that was 35% higher than the mean COL10A1 value in sera of normal individuals (n=32). No significant differences were noted when comparing breast cancer patients to patients with confirmed benign disease suggesting that additional biomarkers may be necessary to discriminate these two populations. Based on this data, *PanC-Dx*TM offered improved performance as compared to the commercially available enzyme-linked immunosorbent assay (ELISA) manufactured with polyclonal antibodies that study investigators previously used in analyzing over 400 serum samples from healthy volunteers and cancer patients. Evaluation of the performance of *PanC-Dx*TM demonstrated 86% area-under-the-curve (AUC) of the Receiver Operating Characteristic (ROC) curve, which determines the level of specificity and sensitivity of the product. The polyclonal ELISA demonstrated 74% AUC of the ROC curve.

"These early data suggest the potential of *PanC-Dx*TM and COL10A1 protein as a blood-based diagnostic and biomarker that could prove useful in non-invasive, early detection of a wide variety of cancers, including breast cancer," said Joseph Wagner, PhD, OncoCyte's Chief Executive Officer. "We are excited by the opportunity of developing *PanC-Dx*TM as a simple, radiation-free alternative for breast cancer detection for millions of women whose dense breast tissue makes their mammograms less accurate. Study investigators are testing other markers in the same patient samples that could increase accuracy for breast cancer detection. In addition, we are encouraged by the potential for *PanC-Dx*TM to detect COL10A1 protein levels with greater sensitivity and specificity than current commercially available assays."

In 2010 over 30 million screening mammograms were performed in the U.S. alone. The American Cancer Society and the National Comprehensive Cancer Network both recommend screening mammography every year starting at age 40, which has been associated with relative reduction in breast cancer mortality of 15% to 20%. However, the NCI estimates that approximately 20% of all breast cancers are not detected by mammography during annual screening, which indicates that there is an unmet need for a breast-cancer screening test with superior specificity and sensitivity when compared to standard screening mammography.

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