

BIOTIME INC
Form 8-K
September 15, 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): **September 15, 2014**

BioTime, Inc.

(Exact name of registrant as specified in its charter)

California

1-12830

94-3127919

(Commission File Number) (IRS Employer

(State or other jurisdiction
of incorporation)

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))

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

On September 15, 2014, our subsidiary OncoCyte Corporation and Abcodia Ltd., a UK-based company focusing on the early detection of cancer, announced their collaboration focused on the development of OncoCyte’s blood-based *PanC-Dx*TM test for early detection of breast cancer. *PanC-Dx*TM is a class of non-invasive cancer diagnostics based on OncoCyte’s proprietary set of cancer markers, which were discovered by company scientists through an analysis of broad gene expression patterns in numerous cancer types. OncoCyte is currently sponsoring four clinical studies of *PanC-Dx*TM in bladder, breast, and lung cancer.

Abcodia has exclusive commercial access to a unique longitudinal biobank of over 5,000,000 serum samples collected through the UK Collaborative Trial for Ovarian Cancer Screening. The biobank was derived from over 200,000 initially healthy volunteers, 50,000 of whom provided samples annually for up to 10 years. Since first recruitment, more than 3,700 individuals have been diagnosed with breast cancer, which generates opportunities to assess serum biomarker changes that occurred years before the diagnosis of breast cancer was made.

The collaboration will begin with an initial study to be completed by the end of 2014. Under the terms of the current agreement, OncoCyte will test the performance of its proprietary *PanC-Dx*TM cancer markers in detecting breast cancer in a set of patient samples selected from the biobank by Abcodia. If the outcome of this initial study is promising, future studies could proceed and expand into the use of a larger cohort to assess OncoCyte’s *PanC-Dx*TM cancer markers in a case-controlled longitudinal design. Because of the very large number of samples in the biobank, it may be possible to execute a very large study of *PanC-Dx*TM much more quickly than otherwise would be possible, potentially accelerating the broad commercialization of the test. The performance of the test in detecting the absence, presence, and development of early breast cancer will be considered in determining the intended use for *PanC-Dx*TM and the regulatory approval pathway that OncoCyte will pursue. As part of the initial collaboration, OncoCyte retains all rights to develop and market its proprietary breast cancer diagnostic products.

The early detection of cancer and its precursors is associated with improved outcomes for patients. Mammography has been widely used since the 1970s for breast cancer screening in asymptomatic women; in 2010 over 30 million screening mammograms were performed in the US alone. Current US National Cancer Institute (NCI) guidelines recommend screening mammograms every 1 to 2 years in women 40 years and older, while the American Cancer Society and the National Comprehensive Cancer Network both recommend screening mammography every year starting at age 40. This screening in women aged 40 to 74 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 there is an unmet need for a breast-cancer screening test with superior specificity and sensitivity when compared to standard screening mammography. *PanC-Dx*TM does not involve radiation exposure and could be indicated for all women regardless of age, and could be performed during the course of regular care with a familiar physician at low cost.

The collaboration with Abcodia represents an expansion of OncoCyte's breast cancer clinical development program, which began early in 2014 with the initiation of an OncoCyte-sponsored 600-patient study at Scottsdale Medical Imaging Laboratories (SMIL) in Scottsdale, Arizona. Data from both studies will be used to support an initial use of the breast cancer diagnostic test by radiologists to aid in determining the malignancy potential of suspicious mammography findings, and by oncologists as a tool for recurrence surveillance in breast-cancer survivors. OncoCyte expects analysis of data from the SMIL cohort should be also completed by the end of 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: September 15, 2014 By: /s/ Michael D. West
Chief Executive Officer